From: Rodriguez, Richard (NIH/NCI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=8092CB5394E04733AC0D4D84D25F65E5-RODRIGR]
Sent: 2/26/2018 8:37:51 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]
Subject: RE: NIH decision to proceed with the license of the anti-CD30 CAR tech to Kite/Gilead

Mark,

Do you have anything you would like to add to this?

Thanks,

Richard

From: Berkley, Dale (NIH/OD) [E]
Sent: Monday, February 26, 2018 2:55 PM
To: Rodriguez, Richard (NIH/NCI) [E] <richard.rodriguez@nih.gov>; Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>
Subject: FW: NIH decision to proceed with the license of the anti-CD30 CAR tech to Kite/Gilead

b5

Dale

Dale D. Berkley, Ph.D., J.D.
Office of the General Counsel, PHD, NIH Branch
Bldg. 31, Rm. 47
Bethesda, MD 20892
301-496-6043
301-402-2528(Fax)

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From: Andrew Goldman [mailto:andrew.goldman@keionline.org]
Sent: Wednesday, February 14, 2018 3:40 PM
To: Lambertson, David (NIH/NCI) [E] <david.lambertson@nih.gov>
Cc: Jamie Love <james.love@keionline.org>; Collins, Francis (NIH/OD) [E] <collinsf@od.nih.gov>
Subject: RE: NIH decision to proceed with the license of the anti-CD30 CAR tech to Kite/Gilead

Dear Dr. Lambertson:

In your email of Jan. 25, 2018 to Knowledge Ecology International, you stated NIH's intention to proceed with the license of anti-CD30 CAR technology to Kite Pharma/Gilead, as noticed in the Federal Register Vol. 82, No. 243, pp. 60406-7.

It is our understanding that under 37 CFR 404.11, there is a right of appeal of "any decision or determination concerning the grant, denial, modification, or termination of a license." Knowledge Ecology International timely filed its comments on this particular proposed license and qualifies for the right of appeal under subsection (a)(3) as a public interest organization representing patients and taxpayers that will be damaged by the agency action.

Please let us know what formal procedures the NIH requires for these appeals, as I did not see relevant guidelines or policies any on the NIH website. If there are none, we will follow up this email with a document detailing the arguments of our appeal.

As a side note, the link to chapter 307 of the HHS Technology Transfer Policies on NIH Procedures for Handling Requests for Reconsideration and Appeals of Licensing Decisions appears to be broken: https://spweb.od.nih.gov/OTT/DTDT/TTPB/US%20PHS%20Technology%20Transfer%20Policy%20Manual/PHS%20TT%20Manual%20Chapters%20-%20Approved%20by%20TTPB/307-Procedure.pdf

Sincerely,

Andrew S. Goldman
Counsel, Policy and Legal Affairs
Knowledge Ecology International
andrew.goldman@keionline.org // www.twitter.com/ASG_KEI
tel.: +1.202.332.2670
www.keionline.org

From: Hammersla, Ann (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=87FB28AA23744C0B855EF0683AC2E8B4-HAMMERSLAA]
Sent: 2/20/2018 1:20:35 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]; Rodriguez, Richard (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8092cb5394e04733ac0d4d84d25f65e5-rodrigr]
Subject: RE: NIH decision to proceed with the license of the anti-CD30 CAR tech to Kite/Gilead

Richard and Mark:

b5

b5 I recommend discussing further with Dale to understand better his recommendation and the risks and advantages of proceeding b5.

Ann

From: Rohrbaugh, Mark (NIH/OD) [E]
Sent: Friday, February 16, 2018 10:50 AM
To: Rodriguez, Richard (NIH/NCI) [E] <richard.rodriguez@nih.gov>
Cc: Hammersla, Ann (NIH/OD) [E] <hammerslaa@mail.nih.gov>
Subject: RE: NIH decision to proceed with the license of the anti-CD30 CAR tech to Kite/Gilead

b5

From: Rodriguez, Richard (NIH/NCI) [E]
Sent: Friday, February 16, 2018 9:34 AM
To: Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>
Cc: Hammersla, Ann (NIH/OD) [E] <hammerslaa@mail.nih.gov>
Subject: FW: NIH decision to proceed with the license of the anti-CD30 CAR tech to Kite/Gilead

Hi Mark,

I wanted to get your thoughts b5 when you had a moment. I'm copying Ann as well. When you have some time, I'd like to have a quick call.

Thanks,

Richard

From: Lambertson, David (NIH/NCI) [E]
Sent: Thursday, February 15, 2018 5:04 PM
To: Rodriguez, Richard (NIH/NCI) [E] <richard.rodriguez@nih.gov>
Subject: FW: NIH decision to proceed with the license of the anti-CD30 CAR tech to Kite/Gilead

Hi Richard,

Regarding the e-mail below, I just spoke with Dale Berkley, and he indicated b5

b5

Please let me know if you would like me to draft a reply to Mr. Goldman for your review before sending it, or if you would prefer to send it yourself.

Thanks,

David A. Lambertson, Ph.D.
Senior Technology Transfer Manager
Technology Transfer Center
National Cancer Institute/NIH
david.lambertson@nih.gov
http://ttc.nci.nih.gov/

9609 Medical Center Drive, Rm 1-E530 MSC 9702
Bethesda, MD 20892-9702 (USPS)
Rockville, MD 20850-9702 (Overnight/express mail)
Phone (Main Office): 240-276-5530
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Fax: 240-276-5504

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From: Andrew Goldman [mailto:andrew.goldman@keionline.org]
Sent: Wednesday, February 14, 2018 3:40 PM

To: Lambertson, David (NIH/NCI) [E] <david.lambertson@nih.gov>
Cc: Jamie Love <james.love@keionline.org>; Collins, Francis (NIH/OD) [E] <collinsf@od.nih.gov>
Subject: RE: NIH decision to proceed with the license of the anti-CD30 CAR tech to Kite/Gilead

Dear Dr. Lambertson:

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Please let us know what formal procedures the NIH requires for these appeals, as I did not see relevant guidelines or policies any on the NIH website. If there are none, we will follow up this email with a document detailing the arguments of our appeal.

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Sincerely,

Andrew S. Goldman
Counsel, Policy and Legal Affairs
Knowledge Ecology International
andrew.goldman@keionline.org // www.twitter.com/ASG_KEI
tel.: +1.202.332.2670
www.keionline.org

From: Berkley, Dale (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5EE461C29F5045A49F0ADF82CAAA2F31-BERKLEYD]
Sent: 2/20/2018 5:10:48 PM
To: Rogers, Karen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b23ef4ca2fa14a6eb174ee611953a396-rogersk]; Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]
Subject: RE: question regarding NIH tech transfer and 40 U.S.C. 559

Thanks Karen.

Dale D. Berkley, Ph.D., J.D.
Office of the General Counsel, PHD, NIH Branch
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From: Rogers, Karen (NIH/OD) [E]
Sent: Tuesday, February 20, 2018 11:55 AM
To: Berkley, Dale (NIH/OD) [E] <berkleyd@od.nih.gov>; Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>
Subject: FW: question regarding NIH tech transfer and 40 U.S.C. 559

Hi Dale and Mark – Just an FYI. This may come your way through the NIH FOIA Office. Karen

From: James Love [mailto:james.love@keionline.org]
Sent: Tuesday, February 20, 2018 11:44 AM
To: Rogers, Karen (NIH/OD) [E] <rogersk@od.nih.gov>
Cc: Andrew Goldman <andrew.goldman@keionline.org>; Thomas, Gina (NIH/OD) [E] <gthomas@od.nih.gov>
Subject: Re: question regarding NIH tech transfer and 40 U.S.C. 559

Ms Rogers. Thank you. We will file a FOIA, asking for documents relating to the 40 USC 559 reviews.

Jamie

On Tue, Feb 20, 2018 at 11:29 AM, Rogers, Karen (NIH/OD) [E] <rogersk@od.nih.gov> wrote:

> Dear Mr. Love – I'm unable to provide you with any additional information for your request. Please submit your inquiry through the NIH FOIA Office.
>
> FOIA Information Office
> NIH Building 31, Room 5B35
> 31 Center Drive, MSC 2107
> Bethesda, MD 20892-2107
>
> Send via email to nihfoia@mail.nih.gov;
>
> or Fax to 301-402-4541.

Regards, Karen

Karen L. Rogers

Acting Director

Office of Technology Transfer

National Institutes of Health

6011 Executive Boulevard, Suite 325

Rockville, MD 20852

E-Mail: RogersK@nih.gov

Phone: 301-435-4359

Fax: 301-402-8678

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From: James Love [mailto:james.love@keionline.org]
Sent: Tuesday, February 20, 2018 10:54 AM
To: Rogers, Karen (NIH/OD) [E] <rogersk@od.nih.gov>
Cc: Andrew Goldman <andrew.goldman@keionline.org>

Subject: Re: question regarding NIH tech transfer and 40 U.S.C. 559

Karen, we are just trying to understand why the NIH thinks that a statute that specially addresses disposals of government owned patents worth more than $3 million does not apply to the disposal of patents that are subject to a statute that applies to all federally owned patents. Sort of makes us wonder which patents 40 U.S.C. 559 is referring to.

Jamie

On Tue, Feb 20, 2018 at 8:21 AM, Rogers, Karen (NIH/OD) [E] <rogersk@od.nih.gov> wrote:

> Dear Mr. Goldman:
>
> Thank you for your email. You will need to obtain your own counsel on this matter, as we can't provide you with legal advice. I think that my previous email was clear regarding our position on the relevance of the statute that you reference.
>
> Regards, Karen
>
> *Karen L. Rogers*
>
> *Acting Director*
>
> *Office of Technology Transfer*
>
> *National Institutes of Health*
>
> *6011 Executive Boulevard, Suite 325*
>
> *Rockville, MD 20852*
>
> *E-Mail: RogersK@nih.gov*
>
> *Phone: 301-435-4359*
>
> *Fax: 301-402-8678*
>
> ***SENSITIVE/CONFIDENTIAL INFORMATION***
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From: Andrew Goldman [mailto:andrew.goldman@keionline.org]
Sent: Thursday, February 15, 2018 11:19 AM
To: Rogers, Karen (NIH/OD) [E] <rogersk@od.nih.gov>
Cc: Jamie Love <james.love@keionline.org>
Subject: Re: question regarding NIH tech transfer and 40 U.S.C. 559

Dear Ms. Rogers:

Thank you for your reply. Could you point me to the legal authority supporting your interpretation? In our reading of the law, patents are clearly included as property subject to the requirements of § 559, the NIH as a federal agency is not exempt from the requirements of the Federal Property and Administrative Services Act, and neither NIH nor DHHS is listed under the very specific list of entities in the section on limitations (40 U.S. Code § 113). Furthermore, "disposal" is not a defined term under the statute, and the Bayh Dole Act contains no exception to the FPASA either in statute or in the regulations that I am aware of.

Sincerely,

Andy

--

Andrew S. Goldman

Counsel, Policy and Legal Affairs

Knowledge Ecology International

andrew.goldman@keionline.org // www.twitter.com/ASG_KEI

tel.: +1.202.332.2670

www.keionline.org

On Thu, Feb 15, 2018 at 8:33 AM, Rogers, Karen (NIH/OD) [E] <rogersk@od.nih.gov> wrote:

Dear Mr. Goldman:

Thank you for your inquiry. The statute you reference is directed to the disposal (assignment) of government property. It has little relevance to our patent licensing activities, which are principally governed by the Bayh-Dole Act and its regulations.

Best regards, Karen

Karen L. Rogers

Acting Director

Office of Technology Transfer

National Institutes of Health

6011 Executive Boulevard, Suite 325

Rockville, MD 20852

E-Mail: RogersK@nih.gov

Phone: 301-435-4359

Fax: 301-402-8678

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From: Andrew Goldman [mailto:andrew.goldman@keionline.org]
Sent: Tuesday, February 13, 2018 11:51 AM
To: Rogers, Karen (NIH/OD) [E] <rogersk@od.nih.gov>; Lambertson, David (NIH/NCI) [E] <david.lambertson@nih.gov>

Cc: Jamie Love <james.love@keionline.org>
Subject: question regarding NIH tech transfer and 40 U.S.C. 559

Dear Ms. Rogers, Mr. Lambertson:

I was hoping you could tell me whether, as required by 40 U.S.C. 559, NIH requests and obtains advice of the Attorney General with respect to antitrust laws prior to transferring patents and related rights from the NIH to private interests?

The relevant sections of 40 U.S.C. 559 are as follows:

> **§559. Advice of Attorney General with respect to antitrust law**
> [...]
> (b) Advice Required.—
> (1) In general.—An executive agency shall not dispose of property to a private interest until the agency has received the advice of the Attorney General on whether the disposal to a private interest would tend to create or maintain a situation inconsistent with antitrust law.
> (2) Exception.—This section does not apply to disposal of—
> (A) real property, if the estimated fair market value is less than $3,000,000; or
> (B) personal property (other than a patent, process, technique, or invention), if the estimated fair market value is less than $3,000,000.
> (c) Notice to Attorney General.—
> (1) In general.—An executive agency that contemplates disposing of property to a private interest shall promptly transmit notice of the proposed disposal, including probable terms and conditions, to the Attorney General.
> (2) Copy.—Except for the General Services Administration, an executive agency that transmits notice under paragraph (1) shall simultaneously transmit a copy of the notice to the Administrator of General Services.
> (d) Advice From Attorney General.—Within a reasonable time, not later than 60 days, after receipt of notice under subsection (c), the Attorney General shall advise the Administrator and any interested executive agency whether, so far as the Attorney General can determine, the proposed disposition would tend to create or maintain a situation inconsistent with antitrust law.
> (e) Request for Information.—On request from the Attorney General, the head of an executive agency shall furnish information the agency possesses that the Attorney General determines is appropriate or necessary to—
> (1) give advice required by this section; or
> (2) determine whether any other disposition or proposed disposition of surplus property violates antitrust law.

The statute's applicability to patents and related property rights is clarified in 41 CFR 102-75.270:

41 CFR 102-75.270 - Must antitrust laws be considered when disposing of property?

Yes, antitrust laws must be considered in any case in which there is contemplated a disposal to any private interest of -

(a) Real and related personal property that has an estimated fair market value of $3 million or more; or

(b) Patents, processes, techniques, or inventions, irrespective of cost.

Sincerely,

Andrew S. Goldman

Counsel, Policy and Legal Affairs

Knowledge Ecology International

andrew.goldman@keionline.org // www.twitter.com/ASG_KEI

tel.: +1.202.332.2670

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--

James Love. Knowledge Ecology International
http://www.keionline.org/donate.html

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twitter.com/jamie_love

--
James Love. Knowledge Ecology International
http://www.keionline.org/donate.html
KEI DC tel: +1.202.332.2670, US Mobile: b6 Geneva Mobile: b6
twitter.com/jamie_love

From: Joe Allen [jallen@allen-assoc.com]
Sent: 12/24/2016 8:49:53 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=OD/cn=ROHRBAUM]
Subject: Revised draft
Attachments: The National Cancer Institute Didn't Deserve Its Treatment in the NY Times.docx

Honed it down some. If you get the chance, let me know if you see any factual errors. Would like to get it to Gene today so he can decide if he wants to go with it next Monday/Tuesday or wait until January.

Thanks!

--

Joseph P. Allen
President
Allen and Associates
60704 Rt. 26, South
Bethesda, OH 43719
(W) 740-484-1814
(c) b6
www.allen-assoc.com

The National Cancer Institute Didn't Deserve Its Treatment By the New York Times

By Joseph P. Allen

Imagine that you found a drug at a government lab that others passed over which promises to cure, not just treat, certain blood cancers. You entered into a cooperative R&D agreement with the lab which doubled their budget for a critical research area while the lab leverages the expertise of your research team. You're a new company taking on the big boys, building a state of the art manufacturing facility in the U.S. hoping to be first to market with a breakthrough therapy.

Now imagine you're a researcher at the National Cancer Institute (NCI, part of the National Institutes of Health) who's been working for years on what could be a breakthrough to meet the mission of the Institute, knowing that it will never benefit desperate patients unless you find a commercial partner. After many years, you find a small company that shares your vision, co-founded by someone who spent time at NCI who deeply respects your research team. They raise millions of dollars for critical clinical trials required to make the research into a useable drug. You've negotiated an agreement which brought funding into NCI for research you were not able to do. Further, if the invention is successful the Institute will receive millions of additional research dollars and the lab inventors will receive a share of the royalties as required by law.

This all sounds pretty good-- but readers can be excused for thinking the public has been ripped off if all they know was from the New York Times article "Harnessing the U.S. Taxpayer to Fight Cancer and Make Profits" (http://www.nytimes.com/2016/12/19/health/harnessing-the-us-taxpayer-to-fight-cancer-and-make-profits.html?action=click&contentCollection=health&region=rank&module=package&version=highlights&contentPlacement=2&pgtype=sectionfront).

The NY Times has been on quite a roll lately (no, not talking about the letter from the Publisher/Executive Editor (http://www.nytimes.com/2016/11/13/us/elections/to-our-readers-from-the-publisher-and-executive-editor.html?_r=0) apologizing for its biased election coverage). A week before the NCI story, they ran a video "Lives and Profits in the Balance: The High Stakes of Medical Patents" (http://www.nytimes.com/2016/12/11/us/retro-report-medical-patents-profits.html) repeating the myth that the government is failing to use the authorities of the Bayh-Dole Act to control drug prices. That's a theme of the NCI story.

The issuance of these articles seems like part of the campaign to pressure NIH to misuse the Bayh-Dole Act for compulsory licenses against drugs deemed too expensive. So let's examine the story's criticisms of the partnership between Kite Pharma and NCI to commercialize a promising immunotherapy discovery:

> *Kite's treatment, a form of immunotherapy called CAR-T, was initially developed by a team of researchers at the National Cancer Institute...*

Not only wasn't the drug "developed" by NCI-- it's not developed. NCI reported their discovery in 2009, followed a year later with mouse studies and a promising single patient study. They later reported data from an expanded clinical study of eight patients. That's a long way from development. Because of Kite's financial backing the drug is in Phase I testing. The odds of any drug going from there to the marketplace are well below 50%. This is the stage where the costs-- and risks-- of drug development increase exponentially. This burden falls squarely on Kite. The other drugs being developed in the partnership are not even at Phase I yet.

> *Kite's first drug, called KTE-C19, could help thousands of patients each year in the United States with certain blood cancers. If it succeeds, it could generate sales of $1 billion to $2 billion annually, according to Wall Street analysts, making it among the most lucrative drugs to come from government research.*

It "could generate sales of $1 billion to $2 billion annually"-- or it could generate nothing. It's too early to know if it's "among the most lucrative drugs to come from government research" or another promising drug that died in clinical trials. When drug trials backed by small companies fail, people lose their jobs and the company may go under. While we don't know the result yet, we do know that without companies like Kite these government-funded discoveries would wither away in the lab.

> *Defenders say that the partnership will likely bring a lifesaving treatment to patients, something the government cannot really do by itself, and that that is what matters most.*
>
> *Critics say that taxpayers will end up paying twice for the same drug — once to support its development and a second time to buy it — while the company reaps the financial benefit.*
>
> *"If this was not a government-funded cancer treatment — if it was for a new solar technology, for example — it would be scandalous to think that some private investors are reaping massive profits off a taxpayer-funded invention," said James Love, director of Knowledge Ecology International, an advocacy group concerned with access to medicines.*

This builds on the myth that the government is developing drugs. Federally funded inventions are early stage discoveries, far removed from being useful products. The risks and expense of commercial development fall on the private sector. In the case of drug development, these expenses often costs hundreds of millions or even billions of dollars with a very high failure rate. It was largely the concern that potentially important medical discoveries were wasting away that led Congress to enact the Bayh-Dole Act creating incentives for industry to partner with universities and federal labs so these discoveries could benefit taxpayers. They are not "paying twice for the same drugs" but finally have an avenue transforming publicly funded research into new products, jobs and companies benefitting the nation and the world.

> *The debate goes squarely to one of the nation's most vexing challenges: rising health care and drug prices. Kite is one of a growing number of drug and biotech companies relying on federal laboratories. Analysts expect the company to charge at least $200,000 for the new treatment, which is intended as a one-time therapy for patients.*
>
> *While the law allows the government to demand drug-price concessions from its private-sector partners, the government has declined to do so with Kite and generally disdains the practice.*

The Bayh-Dole Act only allows agencies to "march-in" requiring compulsory licenses if good faith efforts are not being made to commercialize a federally funded invention or if the licensee cannot produce enough product to meet a national security or health emergency (see NIH Director Collins Stands Up to the March in Mob (http://www.ipwatchdog.com/2016/06/27/nih-director-collins-march-in-mob/id=70391/ and When Government Tried March In Rights to Control Health Care Costs (http://www.ipwatchdog.com/2016/05/02/march-in-rights-health-care-costs/id=68816/). Regardless, persistent efforts are underway to pressure NIH to misapply the law. That appears to be a goal of this story.

> *Insisting on lower prices, federal researchers say, would drive away innovative partners that speed the drug-development process and benefit patients. But with the government doing so much pivotal research, others say that the private sector cannot afford to walk away.*
>
> *"The market is so reliant on the knowledge and know-how that comes out of the government and academic labs," said Dr. Aaron Kesselheim, director of the Program on Regulation, Therapeutics and Law at Brigham & Women's Hospital in Boston. Price curbs, he said, "would not suddenly lead to a total abandonment of this pipeline. It couldn't possibly."*
>
> *Drug makers would be especially unlikely to turn away from immunotherapy, where the promising science has set off a "gold rush mentality," according to Mark Edwards of Bioscience Advisors, a company which tracks pharmaceutical licensing deals.*

But companies did turn away when this was tried previously. In 1989 NIH was pressured into including "reasonable pricing" language in its Cooperative R&D Agreements (CRADAS). The result-- partnerships collapsed and the policy had to be rescinded (https://www.ott.nih.gov/policies-reports). Thinking that because industry sees universities and federal labs as reliable research partners means that we can pull the rug out from under them is not only immoral but short sided. China is targeting the life sciences, pouring billions into their research universities to challenge our lead in basic science. They would welcome with open arms US biotech and drug companies willing to relocate their research activities there. Of course, they are also capable of pulling their own bait and switch after pumping our companies of their expertise.

> *Kite's first drug, called KTE-C19, could help thousands of patients each year in the United States with certain blood cancers. If it succeeds, it could generate sales of $1 billion to $2 billion annually, according to Wall Street analysts, making it among the most lucrative drugs to come from government research.*
>
> *But the government's share of any Kite success would be modest, much lower than some academic research groups have wrangled in immunotherapy deals worth hundreds of millions of dollars.*

NIH negotiated a 5% royalty of Kite's sales. The average university royalty rate is 2% according to data from the Association of University Technology Mangers' 2012 annual report on academic licensing. NIH cannot take an equity as can a university when they spinout companies, but that's irrelevalant-- Kite isn't a spinout. It seems as though NCI negotiated a good deal. Under the law any royalties must be spent on more research and to reward their inventors so such funds support NCI's mission.

> *Under the second type of contract, known as a cooperative research and development agreement, Kite provides money to the N.C.I. to support research. Kite is now paying $3 million a year to Dr. Rosenberg's lab and has provided $7.5 million to it in total since 2012. Based on its regulatory filings, Kite is paying $7.8 million a year for research agreements and licenses in total, with at least $4 million of that going to the cancer institute and the rest to academic or corporate partners.*
>
> *The taxpayer has invested, too. Dr. Rosenberg estimated that the government has spent roughly $10 million over the years on what has become KTE-C19. He said Kite's $3 million a year is about equal to the taxpayer funding in that area and has helped speed research.*

The government's $10 million funding spans many years. NCI significantly increased its research in a critical area of public health because of this partnership.

> *But government officials say few, if any, other companies were interested in the technology at the time Dr. Belldegrun came calling. Dr. Rosenberg said that before Kite, a few companies, including Johnson & Johnson, had looked at an earlier version of his technology but were wary because treatment involved processing each patient's cells.*
>
> *Government-developed technology available to be licensed to companies is posted on the website of the National Institutes of Health. And when the agency intends to grant a license to a particular company, it publishes that in the Federal Register, inviting public comment and possible competing offers. Both steps were taken in the case of Kite, officials said.*

In December 2010 NIH advertised that the inventions were available for licensing. They remained available for two years to any company. NIH published a notice on January, 2012 that it intended to award a license to Kite, inviting public comments. One of the hallmarks of American entrepreneurship is that small companies like Kite seize opportunities passed over by larger companies. If they succeed, good for them. If they fail, they take the hit.

> *Dr. Rosenberg* (NCI researcher) *professes no interest in the business side of the Kite relationship. He does not own stock in any company, even Kite, though he could get up to $150,000 a year in patent royalties if some of Kite's efforts pay off.*

Federal law mandates that inventors must receive a portion of royalties received by government labs. If Dr. Rosenberg has indeed made "*among the most lucrative drugs to come from government research*" then God bless him and his team. It's potentially lucrative because it might be a significant breakthrough protecting public health. It also may fail.

> *The N.I.H. does not take equity positions in companies to avoid an appearance of a conflict of interest. So to critics of the government deals, drug prices are crucial to understanding taxpayer value. After all, they ask, is a drug truly widely available — which is what the government says is its measure of success — if it costs too much for some people?*
>
> *Rachel Sachs, an associate law professor at Washington University in St. Louis and expert in innovation policy, said the government had every right to seek price concessions. She noted that the government, through Medicare and Medicaid, was effectively buying its inventions back from itself. "The public is paying for the research and to the extent that many people, if not most, will pay through public insurance, we're paying again," she said...*
>
> *One mechanism to control pricing already exists. It is called march-in rights, and it lets the N.I.H. take back control of a patent on an invention made with federal funding if the*

> *drug is not being made available to the public on reasonable terms. The tool has gone unused.*

How many new products of any kind could meet the test that they don't "cost too much for some people?" Developing new drugs requires lots of time and money with daunting odds against success, which is why only a handful of countries (primarily in the US) develop them. The public is only paying for early stage research, not for costly commercial development. The genius of our system is that we injected patent incentives into public R&D so companies will assume this risk. When they fail, the company, not the taxpayer, takes the hit. The goal of the Bayh-Dole Act is commercialization, not having the government second guess pricing decisions. If Congress wants that, they must amend the law -- and assume responsibility if the system collapses.

> *Meantime, the relationship between Kite and the National Cancer Institute is expanding to develop treatments for other cancers, including one technique Dr. Rosenberg thinks could be used to attack solid tumors like colon, breast and lung cancer.*
>
> *"The potential for broad applicability is huge," he said.*
>
> *That could mean many lives saved and maybe more billion-dollar drugs for Kite and its investors, with the American taxpayer right in the middle of the deal.*

While it's not unusual to hear citizens sincerely thank those in the military for their service, we should also thank those like Dr. Rosenberg and his colleagues who dedicate their lives to pushing forward the frontiers of science while finding effective ways to alleviate human suffering. That can only happen when their discoveries are commercialized, otherwise they are merely generating interesting research papers.

Rather than the deserved accolades, NCI and Kite Pharma got a pie in the face from the NY Times. Perhaps they'll feel better recalling the words of Jonathan Swift: "When a true genius appears, you can know him by this sign: that all the dunces are in a conspiracy against him." Don't let the dunces get you down-- keep up the good work. Lives depend on it.

From: Berkley, Dale (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5EE461C29F5045A49F0ADF82CAAA2F31-BERKLEYD]
Sent: 8/20/2019 2:58:24 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]; Lambertson, David (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3c95b34f709746a8a2553ce54e74ace2-lambertsond]
Subject: RE: 84 FR 33270, Prospective Grant of an Exclusive Patent License: Allogeneic Therapy Using Bicistronic Chimeric Antigen Receptors Targeting CD19 and CD20; and 84 FR 33272, Prospective Grant of an Exclusive Patent License: Autologus Therapy Using Bicis...

Any of those times work for me. b5

Dale D. Berkley, Ph.D., J.D.
Office of the General Counsel, PHD, NIH Branch
Bldg. 31, Rm. 47
Bethesda, MD 20892
301-496-6043
301-402-2528(Fax)
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From: Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>
Sent: Tuesday, August 20, 2019 10:47 AM
To: Berkley, Dale (NIH/OD) [E] <berkleyd@od.nih.gov>; Lambertson, David (NIH/NCI) [E] <david.lambertson@nih.gov>
Subject: RE: 84 FR 33270, Prospective Grant of an Exclusive Patent License: Allogeneic Therapy Using Bicistronic Chimeric Antigen Receptors Targeting CD19 and CD20; and 84 FR 33272, Prospective Grant of an Exclusive Patent License: Autologus Therapy Using Bicis...

I agree. b5 I am available today for a call 2:230 and then after 4. Tomorrow 1-4 pm

From: Berkley, Dale (NIH/OD) [E] <berkleyd@od.nih.gov>
Sent: Tuesday, August 20, 2019 10:42 AM
To: Lambertson, David (NIH/NCI) [E] <david.lambertson@nih.gov>; Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>
Subject: RE: 84 FR 33270, Prospective Grant of an Exclusive Patent License: Allogeneic Therapy Using Bicistronic Chimeric Antigen Receptors Targeting CD19 and CD20; and 84 FR 33272, Prospective Grant of an Exclusive Patent License: Autologus Therapy Using Bicis...

b5

Dale D. Berkley, Ph.D., J.D.
Office of the General Counsel, PHD, NIH Branch
Bldg. 31, Rm. 47
Bethesda, MD 20892
301-496-6043
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From: Lambertson, David (NIH/NCI) [E] <david.lambertson@nih.gov>
Sent: Monday, August 19, 2019 9:58 AM
To: Berkley, Dale (NIH/OD) [E] <berkleyd@od.nih.gov>
Subject: FW: 84 FR 33270, Prospective Grant of an Exclusive Patent License: Allogeneic Therapy Using Bicistronic Chimeric Antigen Receptors Targeting CD19 and CD20; and 84 FR 33272, Prospective Grant of an Exclusive Patent License: Autologus Therapy Using Bicis...

Good morning Dale,

b5

Thanks,
Dave

David A. Lambertson, Ph.D.
Senior Technology Transfer Manager
Technology Transfer Center
National Cancer Institute/NIH
david.lambertson@nih.gov
http://ttc.nci.nih.gov/

9609 Medical Center Drive, Rm 1-E530 MSC 9702
Bethesda, MD 20892-9702 (USPS)
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Fax: 240-276-5504

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From: James Love <james.love@keionline.org>
Sent: Wednesday, August 14, 2019 11:35 PM
To: Lambertson, David (NIH/NCI) [E] <david.lambertson@nih.gov>
Subject: Re: 84 FR 33270, Prospective Grant of an Exclusive Patent License: Allogeneic Therapy Using Bicistronic Chimeric Antigen Receptors Targeting CD19 and CD20; and 84 FR 33272, Prospective Grant of an Exclusive Patent License: Autologus Therapy Using Bicis...

Dr. Lambertson, thank you for the two letters

Can you tell me what the NIH procedures are for an administrative appeal of this decision?

On Wed, Aug 14, 2019 at 9:11 PM Lambertson, David (NIH/NCI) [E] <david.lambertson@nih.gov> wrote:

> Mr. Love,
>
> Please find attached responses to your objections to Federal Register Notices for both A-366-2019 and A-367-2019.
>
> Regards,

David A. Lambertson, Ph.D.

Senior Technology Transfer Manager

Technology Transfer Center
National Cancer Institute/NIH
david.lambertson@nih.gov

http://ttc.nci.nih.gov/

9609 Medical Center Drive, Rm 1-E530 MSC 9702

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Fax: 240-276-5504

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From: James Love <james.love@keionline.org>
Sent: Monday, July 29, 2019 10:51 PM
To: Lambertson, David (NIH/NCI) [E] <david.lambertson@nih.gov>; Alex Lawson <alawson@socialsecurityworks.org>; Merith Basey <merith@essentialmedicine.org>; Manon Ress <MANON.RESS@cancerunion.org>; Clare Love <claremlove@gmail.com>; Luis Gil Abinader <luis.gil.abinader@keionline.org>; Claire Cassedy <claire.cassedy@keionline.org>; Kathryn Ardizzone <kathryn.ardizzone@keionline.org>
Subject: Re: 84 FR 33270, Prospective Grant of an Exclusive Patent License: Allogeneic Therapy Using Bicistronic Chimeric Antigen Receptors Targeting CD19 and CD20; and 84 FR 33272, Prospective Grant of an Exclusive Patent License: Autologus Therapy Using Bicis...

Dear Dr. Lambertson,

Attached are joint comments from

- Knowledge Ecology International (KEI)

- Social Security Watch (SSW)
- Universities Allied for Essential Medicines (UAEM)
- Union for Affordable Cancer Treatment (UACT)
- Clare Love

on the Gilead/Kite license Bicistronic Chimeric Antigen Receptors Targeting CD19 and CD20 for treatment for the treatment of B-cell derived human cancers.

Jamie

--

James Love. Knowledge Ecology International

U.S. Mobile b6

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http://www.keionline.org

twitter.com/jamie_love

--
James Love. Knowledge Ecology International
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U.S. office phone +1.202.332.2670
http://www.keionline.org
twitter.com/jamie_love

From: Baker, Rebecca (NIH/OD) [E] [/O=NIH/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BAKERRG]
Sent: 11/22/2016 4:59:08 PM
To: Bundesen, Liza (NIH/OD) [E] [/O=NIH/OU=Nihexchange/cn=nimh/cn=lbundese]; Rohrbaugh, Mark (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=OD/cn=ROHRBAUM]
Subject: RE: WF 350339 - due 11/14

Thanks Mark and Liza,

Yes, Kathy and I will go over the package together when it gets here. I'd be happy to go through things with ES too, if there are any questions.

Thanks again,

Rebecca

From: Bundesen, Liza (NIH/OD) [E]
Sent: Tuesday, November 22, 2016 9:15 AM
To: Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>; Baker, Rebecca (NIH/OD) [E] <bakerrg@od.nih.gov>
Subject: RE: WF 350339 - due 11/14

Thanks, Mark! I believe Michelle Whitfield is going to reach out to Rebecca regarding your recommendation.

From: Rohrbaugh, Mark (NIH/OD) [E]
Sent: Monday, November 21, 2016 2:43 PM
To: Bundesen, Liza (NIH/OD) [E] <lbundese@od.nih.gov>; Baker, Rebecca (NIH/OD) [E] <bakerrg@od.nih.gov>
Subject: RE: WF 350339 - due 11/14

b5

Attached are proposed edits.

From: Bundesen, Liza (NIH/OD) [E]
Sent: Monday, November 21, 2016 10:32 AM
To: Baker, Rebecca (NIH/OD) [E] <bakerrg@od.nih.gov>; Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>
Subject: FW: WF 350339 - due 11/14

Hi Rebecca and Mark,

As you know, we have multiple draft responses to KEI regarding Xtandi b5 b5. Per the email trail below and OSP's and OGC's comments, it sounds as though folks are requesting that language

b5

Please let me know if you'd like to chat. I'll be in Building 1 until about 1130, and then I'm heading home to telework.

For reference, I've attached the three incoming letters (the PDFs), and two responses (Word). We'll ultimately recycle the approved language for the third response.

Thanks in advance for your help ☺

Liza

From: Whitfield, Michelle D. (NIH/OD) [E]
Sent: Tuesday, November 15, 2016 12:36 PM
To: Bundesen, Liza (NIH/OD) [E] <lbundese@od.nih.gov>
Cc: Kromash, Dana (NIH/OD) [E] <dana.kromash@nih.gov>
Subject: FW: WF 350339 - due 11/14

Hi Liza,

Please see the e-mails below. Dr. Hudson did meet with KEI. Hopefully Rebecca can help with any other questions you may have about the meeting.

OSP and OGC would also like b5 I am pasting their comments below. I also sent this to OER in DDRMS.

Thank you!
Michelle

OSP
b5

OGC
b5

From: Koeneman, Sandy (NIH/OD) [E]
Sent: Monday, November 14, 2016 2:26 PM
To: Whitfield, Michelle D. (NIH/OD) [E] <whitfieldmd@mail.nih.gov>
Subject: Fwd: WF 350339 - due 11/14

Michelle, please see note from Rebecca below.

Begin forwarded message:

> **From:** "Baker, Rebecca (NIH/OD) [E]" <bakerrg@od.nih.gov>
> **Date:** November 14, 2016 at 2:20:42 PM EST
> **To:** "Koeneman, Sandy (NIH/OD) [E]" <Sandra.Koeneman@nih.gov>, "Allen-Gifford, Patrice (NIH/OD) [E]" <patrice.allen-gifford@nih.gov>
> **Subject: FW: WF 350339 - due 11/14**
>
> Hi Sandy and Patrice,
>
> Could you please make sure that Kathy has an opportunity to review this response before it's sent?

Kathy met with KEI about Xtandi and other issues last week, and will want to be aware of any communications on this topic.

Thanks,
Rebecca

From: Baker, Rebecca (NIH/OD) [E]
Sent: Monday, November 14, 2016 2:19 PM
To: Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>; Wolinetz, Carrie (NIH/OD) [E] <carrie.wolinetz@nih.gov>
Subject: RE: WF 350339 - due 11/14

Hi Mark,

Thanks for sending.
I agree with you that b5
b5

The response as is, though, looks factually correct, so I'll just ask ExecSec to make sure Kathy reviews it before it's sent.

Thanks,
Rebecca

From: Rohrbaugh, Mark (NIH/OD) [E]
Sent: Thursday, November 10, 2016 3:08 PM
To: Baker, Rebecca (NIH/OD) [E] <bakerrg@od.nih.gov>; Wolinetz, Carrie (NIH/OD) [E] <carrie.wolinetz@nih.gov>
Subject: FW: WF 350339 - due 11/14
Importance: High

b5

From: Plude, Denise (NIH/OD) [E]
Sent: Thursday, November 10, 2016 2:58 PM
To: Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>
Subject: WF 350339 - due 11/14
Importance: High

Work Folder Information
Work Folder: WF 350339
Process: Clearance
Program Analyst: Whitfield, Michelle D. (NIH/OD) [E]
Due Date: November 14, 2016
WF Subject: OS direct reply with clearance- Follow-up to #349914. b4
b4

b4

IC: od_osp
From: Davis, PaulKiecken, Brigitte
To: Burwell, SylviaBulls, Michelle
Remarks: Assigned to OCPL, NCI, OSP, OTT, and OGC for clearance by Nov. 14. Draft prepared by OER. Please provide your clearance and/or comments (regarding document named DR1 Rnd1 350339 Draft Response to Paul Davis request to Honorable Sylvia Mathews Burwell dated October 26 in the Draft Response folder) to ES by c.o.b. Nov. 14. Thank you.

From: Myles, Renate (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/CN=RECIPIENTS/CN=MYLESR]
Sent: 1/3/2017 7:43:54 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=OD/cn=ROHRBAUM]
Subject: FW: Interview request: NIH Exclusive Licenses / drug pricing

---

From: Robinson, Michael J (HHS/ASPA)
Sent: Thursday, November 03, 2016 10:18 AM
To: Fine, Amanda (NIH/OD) [E] <amanda.fine@nih.gov>; HHS/OS Interviews <interviews@hhs.gov>; OCOEAOMA-Press (FDA) <OCOEAOMA-Press@fda.hhs.gov>
Cc: Burklow, John (NIH/OD) [E] <BurklowJ@OD.NIH.GOV>; Allen, Marin (NIH/OD) [E] <AllenM1@mail.nih.gov>; Jackson, Calvin (NIH/OD) [E] <JACKSONC@od31tm1.od.nih.gov>; Myles, Renate (NIH/OD) [E] <mylesr@od.nih.gov>; Akinso, Woleola (NIH/OD) [E] <akinsow@od.nih.gov>; Fritz, Craig (NIH/OD) [E] <craig.fritz@nih.gov>; Seigfreid, Kim (NIH/OD) [E] <seigfreidks@od.nih.gov>; Wojtowicz, Emma (NIH/OD) [E] <emma.wojtowicz@nih.gov>; ODOCPL Interviews (NIH/OD OCPL) <ODOCPLInterviews@mail.nih.gov>
Subject: RE: Interview request: NIH Exclusive Licenses / drug pricing

Ok

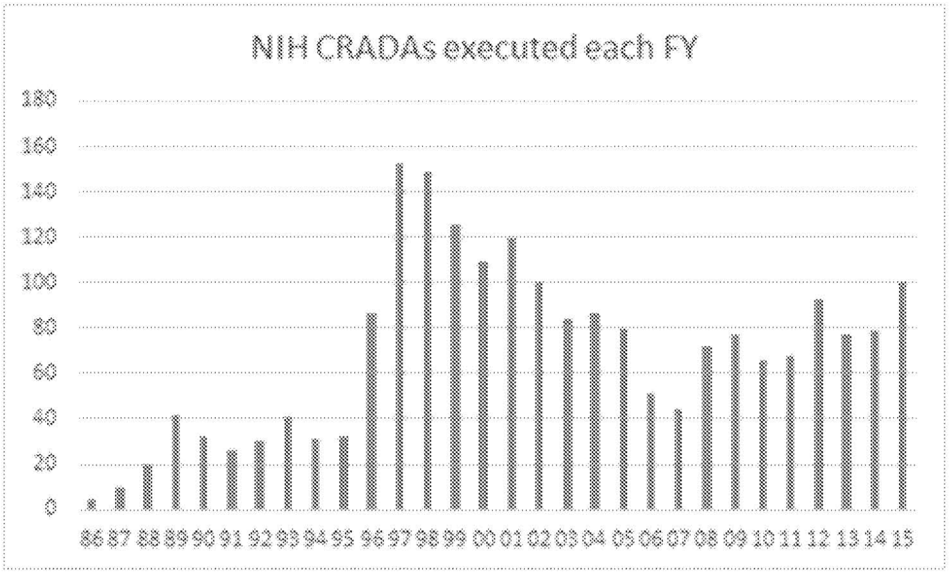
From: Fine, Amanda (NIH/OD) [E] [mailto:amanda.fine@nih.gov]
Sent: Thursday, November 03, 2016 9:56 AM
To: Robinson, Michael J (HHS/ASPA); OS - Interviews; OCOEAOMA-Press (FDA)
Cc: Burklow, John (NIH/OD) [E]; Allen, Marin (NIH/OD) [E]; Jackson, Calvin (NIH/OD) [E]; Myles, Renate (NIH/OD) [E]; Akinso, Woleola (NIH/OD) [E]; Fritz, Craig (NIH/OD) [E]; Seigfreid, Kim (NIH/OD) [E]; Wojtowicz, Emma (NIH/OD) [E]; ODOCPL Interviews (NIH/OD OCPL)
Subject: RE: Interview request: NIH Exclusive Licenses / drug pricing

Add:

Key Messages:

Information about the NIH sponsored clinical trial of which compound chlorcyclizine was a part can be found on clinicaltrials.gov: https://clinicaltrials.gov/ct2/show/NCT02118012?term=NCT02118012&rank=1. Detailed analyses are being performed in preparation for a manuscript, which will describe the whole trial, data analyses and outcome.

Additional information: Dan asked about the trial so we will point him to the page on CT.gov (see above). He also asked for the chart which shows the data over the period of time prior to, during, and after a reasonable pricing clause was included in CRADAS and then eventually removed. Image and caption below.



Source: NIH Office of Technology Transfer. In 1986, the Federal Transfer Act gave NIH the authority to negotiate CRADAs. A reasonable pricing clause was added to NIH CRADAs in 1989 at the direction of the Public Health Service. NIH removed the clause in 1995, after a review of the situation and several public hearings determined that it was hindering collaborations between NIH and industry. Collaborations tripled after that period.

Note: A dip occurred following 2005 because NIH announced that its scientists could no longer engage in outside private consulting with biopharma companies, per Financial Conflict of Interest Rules. Scientists and companies mistakenly believed that this affected their ability to collaborate through a CRADA. Once it was clarified that it did not affect CRADAs, the numbers rebounded.

From: Robinson, Michael J (HHS/ASPA)
Sent: Monday, October 31, 2016 10:57 AM
To: Fine, Amanda (NIH/OD) [E] <amanda.fine@nih.gov>; HHS/OS Interviews <interviews@hhs.gov>; OCOEAOMA-Press (FDA) <OCOEAOMA-Press@fda.hhs.gov>
Cc: Burklow, John (NIH/OD) [E] <BurklowJ@OD.NIH.GOV>; Allen, Marin (NIH/OD) [E] <AllenM1@mail.nih.gov>; Jackson, Calvin (NIH/OD) [E] <JACKSONC@od31tm1.od.nih.gov>; Myles, Renate (NIH/OD) [E] <mylesr@od.nih.gov>; Akinso, Woleola (NIH/OD) [E] <akinsow@od.nih.gov>; Fritz, Craig (NIH/OD) [E] <craig.fritz@nih.gov>; Seigfreid, Kim (NIH/OD) [E] <seigfreidks@od.nih.gov>; Wojtowicz, Emma (NIH/OD) [E] <emma.wojtowicz@nih.gov>; ODOCPL Interviews (NIH/OD OCPL) <ODOCPLInterviews@mail.nih.gov>
Subject: RE: Interview request: NIH Exclusive Licenses / drug pricing

Ok

From: Fine, Amanda (NIH/OD) [E] [mailto:amanda.fine@nih.gov]
Sent: Monday, October 31, 2016 10:54 AM
To: OS - Interviews
Cc: Burklow, John (NIH/OD) [E]; Allen, Marin (NIH/OD) [E]; Jackson, Calvin (NIH/OD) [E]; Myles, Renate (NIH/OD) [E]; Akinso, Woleola (NIH/OD) [E]; Fritz, Craig (NIH/OD) [E]; Seigfreid, Kim (NIH/OD) [E]; Wojtowicz, Emma (NIH/OD) [E]; ODOCPL Interviews (NIH/OD OCPL)
Subject: Interview request: NIH Exclusive Licenses

Reporter: Dan Vergano
Organization: BuzzFeed News
Phone #(s): **b6**
Subject: NIH Exclusive Licenses
Deadline: today, ASAP

Spokesperson: NIH general and Dr. Mark Rohrbaugh is the Special Advisor for Technology Transfer to the NIH Deputy Director for Intramural Research
Expected place of publication (print, online, broadcast): print/online
Expected date of publication/airing: this week
Expected prominence (e.g. front page, Sunday, evening/morning show, etc.): tbd

Key messages/talking points:

In 2014, the NIH Office of Technology Transfer within the NIH Office of the Director broadly advertised the opportunity to take a commercial license on a technology of several new classes of compounds including an antihistamine compound chlorcyclizine for potential new treatment against the hepatitis C virus. Virotas Pharmaceutical, LLC, was the only company to submit an application. Consistent with federal technology transfer law, NIH issued an exclusive license to Virotas Pharmaceutical, LLC, in 2015 to develop the technology with the requirement to commercialize it for the treatment of hepatitis C.

Prior to posting a notice for a proposed granting of an exclusive license, the NIH determines that the criteria set forth in 37 CFR 404.7(a)(1)(ii-iii) have been satisfied and that the company is qualified both technically and financially to be granted an exclusive license to the Government's intellectual property in the fields of use as specified. NIH considers carefully when a technology should have an exclusive or non-exclusive license. Because many, if not most, of the technologies developed at the NIH, FDA and CDC are early stage biomedical technologies, the time, cost and development risks to develop an FDA-approved product [or "drugs and vaccines"] are high. An exclusive license incentivizes companies to invest in the commercial development of early stage NIH, FDA and CDC technology.

On Reasonable Pricing Clause:

It is not within the NIH's mission to evaluate or determine drug pricing. Partnerships between NIH and biomedical companies are critical for translating basic research discoveries into new medical treatments and products. Without industry involvement, NIH scientists could not gain access to industry's materials and expertise to advance their research into potential new treatments. Cooperative Research and Development Agreements (CRADAS) are a mechanism to allow collaborations between NIH investigators and companies to conduct research or facilitate the development of healthcare products. In the late 1989, NIH added a "reasonable pricing clause" to its exclusive licenses including those arising from CRADAS for inventions licensed exclusively for commercialization (not non-exclusively licensed research resources). If the CRADA produced such an invention and the participating company chose to take an exclusive license to that invention, the company would be required to reasonably price the commercialized drug that resulted from the invention. While the clause applied only to NIH commercializable inventions and not research resources, it had a chilling effect on all NIH and industry collaborations. In 1994, NIH held public hearings to consider whether the clause was promoting or constraining NIH's mission to conduct research leading to improved public health. The consensus was that use of the clause was resulting in fewer collaborations to advance research and promising treatments. NIH removed the reasonable pricing clause from the CRADA and its exclusive licenses in 1995 to overcome this road block to collaborations. Once the clause was removed, the number of new collaborations between NIH and industry through a CRADA more than tripled.

Additional information: Dan contacted us after KEI alerted him to communications regarding an exclusive license for the compound chlorcyclizine granted to Virotas Pharmaceutical, LLC: http://keionline.org/node/2219. KEI regularly monitors NIH licensing as drug pricing is one of their top issues. Every time NIH posts on the Federal Register that it will be granting an exclusive license, KEI posts a comment that it does not believe NIH should grant exclusive licenses and that there should be a reasonable pricing clause in the exclusive license.

We will provide the above on background to Dan who will then speak with Mark for further clarification.

Please note, NIH has not received any formal correspondence on KEI about the exclusive license for this compound.

From: Niebylski, Charles (NIH/NIDDK) [E] [/O=NIH/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=NIEBYLSKICD]
Sent: 1/3/2017 6:29:20 PM
To: Amar, Anna (NIH/NCI) [E] [/O=NIH/OU=Nihexchange/cn=niaid/cn=aamar]; Rohrbaugh, Mark (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=OD/cn=ROHRBAUM]
CC: Mowatt, Michael (NIH/NIAID) [E] [/O=NIH/OU=NIHEXCHANGE/cn=NIAID/cn=MMOWATT]; Portilla, Lili (NIH/NCATS) [E] [/O=NIH/OU=NIHEXCHANGE/cn=NHLBIOS/cn=PORTILLL]; Niebylski, Charles (NIH/NIDDK) [E] [/O=NIH/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=Niebylskicd]; McConnell, Cindy (NIH/NCATS) [E] [/O=NIH/OU=NIHEXCHANGE/cn=Recipients/cn=mcconnellc]; Carrera, Krysten (NIH/NIDDK) [E] [/O=NIH/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=Carrerakd]; Harris, Mary (NIH/NIDDK) [E] [/O=NIH/OU=NIHEXCHANGE/cn=NIDDK/cn=HarrisMM]; Chang, Kevin (NIH/NCI) [E] [/O=NIH/OU=NIHEXCHANGE/cn=RECIPIENTS/cn=CHANGKE]; Lambert, Richard (NIH/NIAID) [C] [/O=NIH/OU=NIHEXCHANGE/cn=NIAID/cn=LAMBERTR]
Subject: Re: BuzzFeed News: If Taxpayers Invent A Drug, Should The Government Just Give It Away?
Attachments: image005.jpg; image006.png

Background: This information was released in November as part of NIH's response to a FOIA request from KEI, a non-profit. Curiously, it does not appear that KEI posted any of this FOIA response on their website http://www.keionline.org, as they often do with other NIH responses It would appear that KEI channeled the FOIA information directly to buzzfeed (a for-profit company) and we are now seeing news exposure via an "independent and unaffiliated" media outlet.
Chuck

From: Anna Amar <anna.amar@nih.gov>
Date: Tuesday, January 3, 2017 at 12:26 PM
To: "Rohrbaugh, Mark (NIH/OD) [E]" <RohrBauM@OD.NIH.GOV>
Cc: Michael Mowatt <MMOWATT@niaid.nih.gov>, Lili Portilla <portilll@mail.nih.gov>, "Niebylski, Charles (NIH/NIDDK) [E]" <niebylskicd@niddk.nih.gov>, "McConnell, Cindy (NIH/NCATS) [E]" <mcconnellc@mail.nih.gov>, Krysten Carrera <krysten.carrera@nih.gov>, "Harris, Mary (NIH/NIDDK) [E]" <HarrisMM@extra.niddk.nih.gov>, Kevin Chang <changke@mail.nih.gov>, Richard Lambert <lambertr@niaid.nih.gov>
Subject: RE: BuzzFeed News: If Taxpayers Invent A Drug, Should The Government Just Give It Away?

Mark,

On further investigation, the BuzzFeed website has published the email from Lili Portilla that includes the excerpts they took from me as well as comments from Kevin Chang, and Chuck Niebylski: https://www.documentcloud.org/documents/3245395-Reasonable-Pricing-Virotas-NIH-1.html.

Yes - as you said - the comments in the article are twisted to make it sound like we are only interested in a licensing profit when actually this company was one of the few who wanted to license it - which is the only way it would ever get developed and thereby to the public for the treatment of Hep. C.

Let me know what response, if any, will be made and if I can do anything to help.

-----Original Message-----
From: Rohrbaugh, Mark (NIH/OD) [E]
Sent: Tuesday, January 03, 2017 12:07 PM
To: Amar, Anna (NIH/NCI) [E] <anna.amar@nih.gov>; Lambert, Richard (NIH/NIAID) [C] <lambertr@niaid.nih.gov>
Cc: Mowatt, Michael (NIH/NIAID) [E] <MMOWATT@niaid.nih.gov>
Subject: RE: [Ip-health] BuzzFeed News: If Taxpayers Invent A Drug, Should The Government Just Give It Away?

It must be FOIA. Do you remember a FOIA that captured your emails in the last 2 years?
They spin what you said. The quote about the [greatest] return to the public is the product is what I said, but I also said there is a financial return in royalties. Is the rest accurate?
Joe Allen is working on a response to the last NYTimes article about Dr. Rosenberg.

b5

-----Original Message-----
From: Amar, Anna (NIH/NCI) [E]
Sent: Tuesday, January 03, 2017 11:59 AM
To: Lambert, Richard (NIH/NIAID) [C] <lambertr@niaid.nih.gov>; Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>
Cc: Mowatt, Michael (NIH/NIAID) [E] <MMOWATT@niaid.nih.gov>
Subject: RE: [Ip-health] BuzzFeed News: If Taxpayers Invent A Drug, Should The Government Just Give It Away?

Wow - I don't even know if I said it like that!!

I wonder how it ended up there? FOIA?

Mark: are your "statements" accurate?

Should there be a response to this BussFeed Article?

-----Original Message-----
From: Lambert, Richard (NIH/NIAID) [C]
Sent: Tuesday, January 03, 2017 11:35 AM
To: Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>; Mowatt, Michael (NIH/NIAID) [E] <MMOWATT@niaid.nih.gov>; Amar, Anna (NIH/NCI) [E] <anna.amar@nih.gov>
Subject: FW: [Ip-health] BuzzFeed News: If Taxpayers Invent A Drug, Should The Government Just Give It Away?

FYI

Richard A. Lambert
Contractor
National Institute of Allergy and Infectious Diseases National Institutes of Health U.S. Department of Health and Human Services
5601 Fishers Lane, Rm. 2G47, MSC 9804
Bethesda, MD 20892-9804
(Courier: Rockville, MD. 20852)
301.496.2644 main officeline
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lambertr@niaid.nih.gov

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-----Original Message-----
From: Zack Struver [mailto:zack.struver@keionline.org]

Sent: Tuesday, January 03, 2017 11:18 AM
To: Ip-health <ip-health@lists.keionline.org>
Subject: [Ip-health] BuzzFeed News: If Taxpayers Invent A Drug, Should The Government Just Give It Away?

https://www.buzzfeed.com/danvergano/nih-drug-giveaway

If Taxpayers Invent A Drug, Should The Government Just Give It Away?

When National Institutes of Health gave away a taxpayer-funded Hepatitis C drug, officials brushed aside requests to limit the price charged to consumers.

posted on Dec. 31, 2016, at 11:24 a.m.

Dan Vergano
BuzzFeed News Reporter

Lydia Polimeni, NIH

What if the taxpayer money invented a better treatment for hepatitis, and then just gave it away?

Officials at the National Institutes of Health said that's exactly how it's supposed to work, when queried over public records that show the federal research agency licensed out a potential new hepatitis drug while spurning calls to require the company to set "reasonable prices" for consumers.

"It would be unfortunate," an NIH official, Anna Amar, wrote in a 2015 email, if questioning of the deal by public interest groups, "bothers the company enough to reconsider the license."

In spite of the questions, the NIH completed the licensing deal with an unknown start-up called Virotas LLC in April of 2015. It was one of about 80 such cooperative research and development agreements (CRADA's) that the federal research agency signs every year.

"All we are doing is asking some reasonable questions about giving away the rights to a promising drug," James Love of public interest group Knowledge Ecology International, told BuzzFeed News. "Why would you exclusively license the rights to a promising drug to an unknown firm with no track record?"

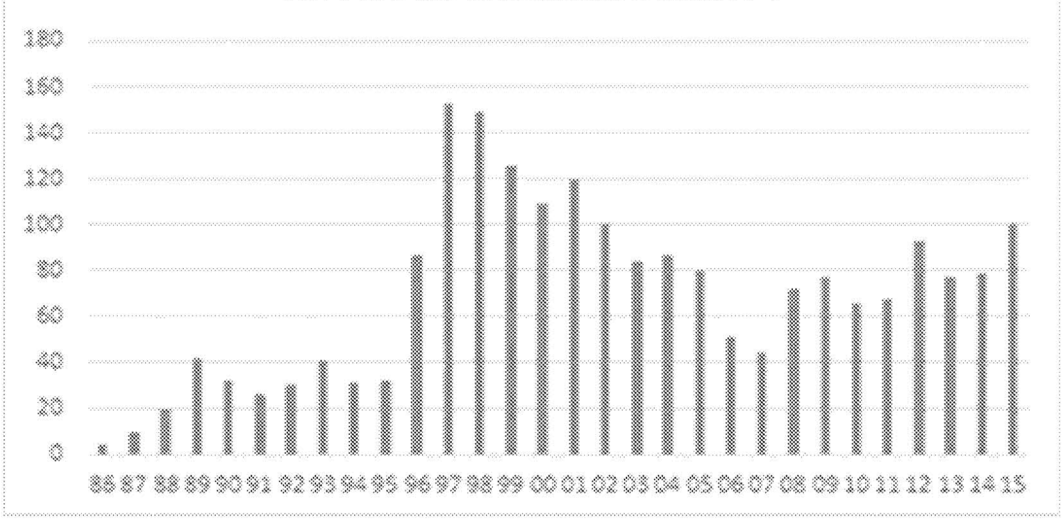
The dispute "is not the first time someone has raised questions over NIH's method of giving exclusive rights to promising drugs," Washington University law professor Rachel Sachs told BuzzFeed News. Since the 1980's, health policy experts have asked why the NIH, the $31 billion federal powerhouse behind the US biomedical research system, doesn't claw back more money from the pharmaceutical industry, where profit margins are rivaled only by banking.

"Somebody has to put pressure on them," Sachs said. "KEI is asking the right questions here."

In the case of chlorcyclizine, National Institute of Diabetes and Digestive and Kidney Diseases researcher T. Jake Liang has shown that the forty-year old drug limits hepatitis in mice. The results showed enough promise against Hepatitis C — a virus that infects about 3 million people nationwide — that NIH funded a 50-patient safety trial of the drug, which is fairly unusual for the basic research institute. (That human trial ended in September, with results still under analysis.)

The drug's licensing last year came just as a debate over the high price of some new hepatitis drugs, notably Gilead Pharmaceuticals' $84,000 Sovaldi, attracted the eye of Congress. A Senate Finance Committee investigation last year found that Gilead employed "a calculated scheme for pricing and marketing its Hepatitis C drug based on one primary goal, maximizing revenue, regardless of the human consequences," according to Sen. Ron Wyden of Oregon. Given such controversies, it's tone deaf at the least to exclusively license a new hepatitis drug to a small firm without any promise of reasonable prices for taxpayers, Love said. Public records released to his group in October show that within the NIH, questions were raised about a response to the reasonable price request, but were ultimately brushed off as beyond the mission of the research institute.

"We take it seriously, but it is not our mission to control drug prices," NIH technology transfer chief Mark Rohrbaugh told BuzzFeed News. Previous efforts to work price restrictions into such agreements scared away firms and ended in 1995, he said. Licensing more than tripled afterwards, with one of the best-known licensing successes, a blood vessel collar coated with a chemotherapy drug that spares patients from heart bypass surgery, coming in 2004.



NIH

"The return to taxpayers is new drugs to the public," Rohrbaugh said.

The license agreement for chlorcyclizine requires the company to pay nothing up front, committing only to pay the NIH an 8% royalty rate on any profits from the drug, with up to $150,000 going directly to the scientists who discovered it. About two dozen staff scientists collect this top number every year at NIH, although the average royalty to staffers there is only $9,000. In 2014 the NIH collected $147 million in royalties from all of its licenses, which includes medical tests and biological materials as well as drugs.

The advocacy group also requested the NIH allow outside researchers continue to look for new uses of the drug, make the research spending that Virotas does transparent to taxpayers, and allow the World Health Organization (WHO) to request a royalty-free license for NIH inventions. A WHO survey in April concluded that the newest hepatitis drugs were essentially “unaffordable” in 12 countries, such as Turkey and Egypt, where prices exceeded the average yearly income.

NIH staff vetted the firm’s ability to shepherd a promising drug through the Food and Drug Administration’s approval process, Rohrbaugh said. Fewer than 3 in 10 drugs that makes it as far as starting human volunteer testing runs this gantlet, where full blown trials can cost tens of millions of dollars apiece. The high cost of getting a drug approved means companies are unlikely to invest in licenses that come with price restrictions, he said.

Nevertheless, the US government retains “march in” rights on drugs to make them affordable, Annette Gaudino of the Treatment Action Group told BuzzFeed News by email. But those rights have only been used in wartime or after bioterrorism events. Refusal to intervene in the case of costly drugs, or to cut off unreasonable prices before they start with licenses, she said, raises questions about NIH’s rationale for licensing drugs.

“Costs are real, but price is a choice,” Gaudino said. “This gets right to the heart of what government is for: To intervene when necessary to preserve the common good, or to smooth the way for entrenched interests?”

But even if the NIH made “reasonable price” requirements a part of its drug licenses, it might not make a difference, said David Evans of Project Inform, an advocacy group for affordable HIV and hepatitis drugs.

“What we claim is the price of a drug, whether it’s $84,000 or $300,000 is almost meaningless,” he told BuzzFeed News. “Drug pricing in the US is so complicated,” he said, because in reality there isn’t really a free market for drugs, but a bewildering kaleidoscope of agreements between hospitals, insurers, clinics, and federal programs such as Medicare, all paying different discounts and rates for medicine.

Some very expensive drugs are sold at deep discount to clinics for low-income patients, Evans noted, and forcing a uniform price on them, might actually raise the price for the most vulnerable. “That makes prices a very difficult calculation for anyone to make, much less asking folks inside NIH to figure it out.”

For that reason, Love suggested that NIH get out of the drug licensing business and that such deals should be handled by the Treasury Department or Medicare accountants more interested in the bottom line. “Other countries are paying less for these drugs we paid to invent,” Love said. “There should be some limits.”

--

Zack Struver, Communications and Research Associate Knowledge Ecology International zack.struver@keionline.org
Twitter: @zstruver <https://twitter.com/zstruver>
Office: +1 (202) 332-2670 Cell: +1 (914) 582-1428 keionline.org

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Ip-health mailing list

Ip-health@lists.keionline.org
http://lists.keionline.org/mailman/listinfo/ip-health_lists.keionline.org

---

From: Rogers, Karen (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B23EF4CA2FA14A6EB174EE611953A396-ROGERSK]
Sent: 2/15/2018 9:49:22 PM
To: Gottesman, Michael (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=918c2344931542a592d00dbe83d3d5a3-gottesmm]; Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]
Subject: FW: question regarding NIH tech transfer and 40 U.S.C. 559

Good Afternoon Dr. Gottesman and Mark – Dave Lambertson (NCI TT) and I received an inquiry from KEI. NCI determined that this was a policy issue and asked OTT to respond. I replied to KEI after getting guidance from Mark and Dale. KEI has come back with a follow-up question. Since KEI has historically published some of our responses and appears to be pushing the issue, I wanted to touch base with you for your review before I reply again b5 b5. Regards, Karen

Karen L. Rogers
Acting Director
Office of Technology Transfer
National Institutes of Health
6011 Executive Boulevard, Suite 325
Rockville, MD 20852
E-Mail: RogersK@nih.gov
Phone: 301-435-4359
Fax: 301-402-8678

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From: Berkley, Dale (NIH/OD) [E]
Sent: Thursday, February 15, 2018 12:55 PM
To: Rogers, Karen (NIH/OD) [E] <rogersk@od.nih.gov>
Subject: RE: question regarding NIH tech transfer and 40 U.S.C. 559

b5

reference.

Best regards, Karen”

Dale D. Berkley, Ph.D., J.D.
Office of the General Counsel, PHD, NIH Branch
Bldg. 31, Rm. 47
Bethesda, MD 20892
301-496-6043
301-402-2528(Fax)

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From: Rogers, Karen (NIH/OD) [E]
Sent: Thursday, February 15, 2018 11:25 AM
To: Berkley, Dale (NIH/OD) [E] <berkleyd@od.nih.gov>
Subject: FW: question regarding NIH tech transfer and 40 U.S.C. 559

Hi Dale – **b5** Regards, Karen

Karen L. Rogers
Acting Director
Office of Technology Transfer
National Institutes of Health
6011 Executive Boulevard, Suite 325
Rockville, MD 20852
E-Mail: RogersK@nih.gov
Phone: 301-435-4359
Fax: 301-402-8678

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From: Andrew Goldman [mailto:andrew.goldman@keionline.org]
Sent: Thursday, February 15, 2018 11:19 AM
To: Rogers, Karen (NIH/OD) [E] <rogersk@od.nih.gov>
Cc: Jamie Love <james.love@keionline.org>
Subject: Re: question regarding NIH tech transfer and 40 U.S.C. 559

Dear Ms. Rogers:

Thank you for your reply. Could you point me to the legal authority supporting your interpretation? In our reading of the law, patents are clearly included as property subject to the requirements of § 559, the NIH as a federal agency is not exempt from the requirements of the Federal Property and Administrative Services Act, and neither NIH nor DHHS is listed under the very specific list of entities in the section on limitations (40 U.S. Code § 113). Furthermore, "disposal" is not a defined term under the statute, and the Bayh Dole Act contains no exception to the FPASA either in statute or in the regulations that I am aware of.

Sincerely,
Andy

--
Andrew S. Goldman

Counsel, Policy and Legal Affairs
Knowledge Ecology International
andrew.goldman@keionline.org // www.twitter.com/ASG_KEI
tel.: +1.202.332.2670
www.keionline.org

On Thu, Feb 15, 2018 at 8:33 AM, Rogers, Karen (NIH/OD) [E] <rogersk@od.nih.gov> wrote:

> Dear Mr. Goldman:
>
> Thank you for your inquiry. The statute you reference is directed to the disposal (assignment) of government property. It has little relevance to our patent licensing activities, which are principally governed by the Bayh-Dole Act and its regulations.
>
> Best regards, Karen
>
> *Karen L. Rogers*
>
> *Acting Director*
>
> *Office of Technology Transfer*
>
> *National Institutes of Health*
>
> *6011 Executive Boulevard, Suite 325*
>
> *Rockville, MD 20852*
>
> *E-Mail: RogersK@nih.gov*
>
> *Phone: 301-435-4359*
>
> *Fax: 301-402-8678*
>
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From: Andrew Goldman [mailto:andrew.goldman@keionline.org]
Sent: Tuesday, February 13, 2018 11:51 AM
To: Rogers, Karen (NIH/OD) [E] <rogersk@od.nih.gov>; Lambertson, David (NIH/NCI) [E] <david.lambertson@nih.gov>
Cc: Jamie Love <james.love@keionline.org>
Subject: question regarding NIH tech transfer and 40 U.S.C. 559

Dear Ms. Rogers, Mr. Lambertson:

I was hoping you could tell me whether, as required by 40 U.S.C. 559, NIH requests and obtains advice of the Attorney General with respect to antitrust laws prior to transferring patents and related rights from the NIH to private interests?

The relevant sections of 40 U.S.C. 559 are as follows:

> **§559. Advice of Attorney General with respect to antitrust law**
> [...]
> (b) Advice Required.—
> (1) In general.—An executive agency shall not dispose of property to a private interest until the agency has received the advice of the Attorney General on whether the disposal to a private interest would tend to create or maintain a situation inconsistent with antitrust law.
> (2) Exception.—This section does not apply to disposal of—
> (A) real property, if the estimated fair market value is less than $3,000,000; or
> (B) personal property (other than a patent, process, technique, or invention), if the estimated fair market value is less than $3,000,000.
> (c) Notice to Attorney General.—
> (1) In general.—An executive agency that contemplates disposing of property to a private interest shall promptly transmit notice of the proposed disposal, including probable terms and conditions, to the Attorney General.
> (2) Copy.—Except for the General Services Administration, an executive agency that transmits notice under paragraph (1) shall simultaneously transmit a copy of the notice to the Administrator of General Services.
> (d) Advice From Attorney General.—Within a reasonable time, not later than 60 days, after receipt of notice under subsection (c), the Attorney General shall advise the Administrator and any interested executive agency whether, so far as the Attorney General can determine, the proposed disposition would tend to create or maintain a situation inconsistent with antitrust law.
> (e) Request for Information.—On request from the Attorney General, the head of an executive agency shall furnish information the agency possesses that the Attorney General determines is appropriate or necessary to—
> (1) give advice required by this section; or

> (2) determine whether any other disposition or proposed disposition of surplus property violates antitrust law.

The statute's applicability to patents and related property rights is clarified in 41 CFR 102-75.270:

> **41 CFR 102-75.270 - Must antitrust laws be considered when disposing of property?**
>
> Yes, antitrust laws must be considered in any case in which there is contemplated a disposal to any private interest of -
>
> (a) Real and related personal property that has an estimated fair market value of $3 million or more; or
>
> (b) Patents, processes, techniques, or inventions, irrespective of cost.

Sincerely,

Andrew S. Goldman

Counsel, Policy and Legal Affairs

Knowledge Ecology International

andrew.goldman@keionline.org // www.twitter.com/ASG_KEI

tel.: +1.202.332.2670

www.keionline.org

From: Rita Khanna b6
Sent: 11/21/2016 8:50:37 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=OD/cn=ROHRBAUM]
Subject: Re: Moving to a new position at NIH

Sounds great, looking forward to seeing you tomorrow. Thanks,
Rita

On Mon, Nov 21, 2016 at 2:44 PM, Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@od.nih.gov> wrote:

> I have an interesting additional policy issue that I will discuss. The NIH had a request related to the June march-in decision on Xtandi. KEI and a Canadian company modified their request by asking for NIH to use its government use license to permit the company to produce generic drug for sale and distribution in low and middle income countries where it is either unavailable or expensive.
>
> **From:** Rita Khanna [mailto: b6
> **Sent:** Monday, November 21, 2016 2:36 PM
>
> **To:** Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>
> **Subject:** Re: Moving to a new position at NIH
>
> An hour or so for lecture and 30 minutes for discussion.
>
> On Mon, Nov 21, 2016 at 12:53 PM, Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@od.nih.gov> wrote:
>
>> How much time do I have?
>>
>> **From:** Rita Khanna [mailto: b6
>> **Sent:** Monday, November 21, 2016 12:47 PM
>>
>> **To:** Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>
>> **Subject:** Re: Moving to a new position at NIH
>>
>> And it is at 5:30pm tomorrow (22Nov2016).
>>
>> On Mon, Nov 21, 2016 at 12:44 PM, Khanna, Rita <RKhanna@aeras.org> wrote:

Mark,

You can talk about OTT's license deals with a focus on developing countries (similar to your previous lecture in this course) and also any related stuff you are doing in your current position.

Best regards,

Rita

From: Rohrbaugh, Mark (NIH/OD) [E] [mailto:RohrBauM@OD.NIH.GOV]
Sent: Monday, November 21, 2016 12:27 PM
To: Khanna, Rita
Subject: RE: Moving to a new position at NIH

Rita:

What would you like me to cover tomorrow night? 5:30 OTT?

Regards,

Mark

From: Khanna, Rita [mailto:RKhanna@Aeras.org]
Sent: Wednesday, October 19, 2016 7:39 PM
To: Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>
Subject: Re: Moving to a new position at NIH

Okay, thanks.

------ Original message------

From: Rohrbaugh, Mark (NIH/OD) [E]

Date: Wed, Oct 19, 2016 6:22 PM

To: Khanna, Rita;

Cc:

Subject: RE: Moving to a new position at NIH

Nov 22 please

From: Khanna, Rita [mailto:RKhanna@Aeras.org]
Sent: Wednesday, October 19, 2016 5:39 PM
To: Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>
Subject: RE: Moving to a new position at NIH

Mark, Just wanted to be sure you received the dates I sent to you on Monday. Best,
Rita

From: Khanna, Rita
Sent: Monday, October 17, 2016 7:29 AM
To: Rohrbaugh, Mark (NIH/OD) [E]
Subject: RE: Moving to a new position at NIH

Mark,

I have following dates available:

October 25, November 22or 29. Let me know what works for you.

Regards,

Rita

From: Rohrbaugh, Mark (NIH/OD) [E] [RohrBauM@OD.NIH.GOV]
Sent: Saturday, October 15, 2016 5:32 PM
To: Khanna, Rita
Subject: Re: Moving to a new position at NIH

Rita:

I could do it then but any chance you have a week or 2 later?

Sent from my iPhone

On Oct 14, 2016, at 2:45 PM, Khanna, Rita <RKhanna@Aeras.org> wrote:

Mark,

Thanks Mark. It has been so much fun and excitement spending time with our first b6

I am signing you up to give a lecture to the class on November 8th.

Best regards,

Rita

From: Rohrbaugh, Mark (NIH/OD) [E] [mailto:RohrBauM@OD.NIH.GOV]
Sent: Wednesday, October 12, 2016 6:25 PM
To: Khanna, Rita
Subject: Re: Moving to a new position at NIH

Rita:

Good to hear from you. Congrats on your b6.

Yes, I am available except for the week of Oct 24.

Regards

Mark

Sent from my iPhone

On Oct 12, 2016, at 4:47 PM, Khanna, Rita <RKhanna@Aeras.org> wrote:

Dear Mark,

Hope you are doing well. Haven't been in touch for a long time.

Would you be interested in giving a lecture to the FAES class I am teaching again this Fall? Also, let me if you are available to meet for lunch some time.

Best,

Rita

From: Rohrbaugh, Mark (NIH/OD) [E] [mailto:RohrBauM@OD.NIH.GOV]
Sent: Monday, November 03, 2014 2:55 PM
To: Khanna, Rita
Subject: RE: Moving to a new position at NIH

Sukrea

From: Khanna, Rita [mailto:RKhanna@Aeras.org]
Sent: Monday, November 03, 2014 2:53 PM
To: Rohrbaugh, Mark (NIH/OD) [E]
Subject: RE: Moving to a new position at NIH

Dear Mark,

Congratulations on your new position!

The NIH Office of the Director will greatly benefit from having you in the role of a Senior Advisor for Technology Transfer.

Good luck in your new endeavor.

Best regards,

Rita

From: Rohrbaugh, Mark (NIH/OD) [E] [mailto:RohrBauM@OD.NIH.GOV]
Sent: Monday, November 03, 2014 11:33 AM
To: Rohrbaugh, Mark (NIH/OD) [E]
Subject: Moving to a new position at NIH

Dear Friends and Colleagues:

I write to provide an update on my new position at NIH. I have moved from the position as Director, Office of Technology Transfer, to Senior Advisor for Technology Transfer in the NIH Office of the Director. I will be working with Dr. Gottesman, Deputy Director for Intramural Research, on intramural matters and Dr. Kathy Hudson, Deputy Director for Science, Outreach, and Policy, on broader technology transfer policy matters. As I look forward to these new responsibilities, I thank you for your assistance to me personally and for your support of the NIH technology transfer program over the years. My contact information may be found in the attached card.

If you need to contact the Office of Technology Transfer, you may call the Acting Director, Richard Rodriguez, or the Deputy Director, Bonny Harbinger, at 301-594-7700. As some of you know, the NIH technology transfer program is undergoing a reorganization through this coming year in which the patenting and licensing of inventions will be moved from the central office to about 6 NIH Institutes, which will conduct the full complement of their own technology transfer operations as well as, in some cases, manage the work of smaller Institutes as a Service Center. Some remaining functions will be retained by the central Office of Technology Transfer. If you need assistance in contacting the appropriate person or office, particularly during this transition, feel free to contact me for assistance.

Sincerely,

Mark

-<image001.jpg>

From: Rohrbaugh, Mark (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/CN=OD/CN=ROHRBAUM]
Sent: 1/3/2017 9:35:50 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=OD/cn=ROHRBAUM]
Subject: RE: Jamie Love's event

Not sure if I sent this
https://www.ott.nih.gov/sites/default/files/documents/pdfs/NIH-Notice-Rescinding-Reasonable-Pricing-Clause.pdf

From: Rohrbaugh, Mark (NIH/OD) [E]
Sent: Thursday, December 29, 2016 10:25 AM
To: Joe Allen <jallen@allen-assoc.com>
Subject: Re: Jamie Love's event

Could you send it back to me? Can't get it from home.

Sent from my iPhone

On Dec 29, 2016, at 10:22 AM, Joe Allen <jallen@allen-assoc.com> wrote:

> Since I had a couple of days before it's published, honed the article down some more and changed the ending. If you find a link to the press release announcing the repeal of the reasonable pricing clause, please pass it along. I link to show where quotes came from wherever possible.
>
> Happy New Year!
>
> On 12/29/2016 9:30 AM, Rohrbaugh, Mark (NIH/OD) [E] wrote:
>
> > I am sure Bob can reschedule to accommodate other invitations you may receive.
> >
> > Sent from my iPhone
> >
> > On Dec 29, 2016, at 7:00 AM, Hammersla, Ann (NIH/OD) [E] <hammerslaa@mail.nih.gov> wrote:
> >
> > > Speaking of being eliminated – I am planning on going to the COGR meeting to be available to discuss changes in BD and data. Ann
> > >
> > > **From:** Joe Allen [mailto:jallen@allen-assoc.com]
> > > **Sent:** Tuesday, December 27, 2016 4:42 PM
> > > **To:** Robert Hardy <RHardy@COGR.edu>; Hammersla, Ann (NIH/OD) [E] <hammerslaa@mail.nih.gov>; Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>
> > > **Subject:** Re: Jamie Love's event
> > >
> > > Guess it's down to Ann. So does anyone know Jay Thomas who Jamie has on the Bayh-Dole panel?

On 12/27/2016 4:37 PM, Robert Hardy wrote:

> Actually it's a direct conflict with our February COGR meeting, so I'm afraid that eliminates me.
>
> Sent via the Samsung GALAXY S® 5, an AT&T 4G LTE smartphone
>
> -------- Original message --------
> From: Joe Allen <jallen@allen-assoc.com>
> Date:12/27/2016 3:45 PM (GMT-05:00)
> To: "Hammersla, Ann (NIH/OD) [E]" <hammerslaa@mail.nih.gov>, "Rohrbaugh, Mark (NIH/OD) [E]" <RohrBauM@OD.NIH.GOV>
> Cc: Robert Hardy <RHardy@COGR.edu>
> Subject: Re: Jamie Love's event
>
> Looks like Ann and Bob are available. Want me to pass that along to Jamie?
>
> On 12/27/2016 2:19 PM, Hammersla, Ann (NIH/OD) [E] wrote:
>
>> Not sure if your stories of your February commitment are believable...........
>>
>> **From:** Rohrbaugh, Mark (NIH/OD) [E]
>> **Sent:** Tuesday, December 27, 2016 2:07 PM
>> **To:** Joe Allen <jallen@allen-assoc.com>
>> **Cc:** Hammersla, Ann (NIH/OD) [E] <hammerslaa@mail.nih.gov>; Robert Hardy <RHardy@COGR.edu>
>> **Subject:** Re: Jamie Love's event
>>
>> funny, I just got a federal court juror summons for February, seriously.
>>
>> Sent from my iPhone
>>
>> On Dec 27, 2016, at 10:47 AM, Joe Allen <jallen@allen-assoc.com> wrote:
>>
>>> This is the only time I felt relief (sort of) to get a summons for federal grand jury duty in February, so told Jamie that I

couldn't attend. You can see below what he has in mind. I don't know Jay Thomas, do you? Looks like Mark can expect an invitation (if you'd rather join me on a grand jury in Columbus, OH let me know...)

Happy New Year

-------- Forwarded Message --------

Subject: Re: Panel on Bayh-Dole march-in
Date: Tue, 20 Dec 2016 11:04:39 -0500
From: Jamie Love <james.love@keionline.org>
To: Joe Allen <jallen@allen-assoc.com>

Joe, we are going to do a 1/2 day or full data meeting on compulsory licensing of patents. It will be technical, and policy wonk type of thing. The point is to invite people who know stuff on the topic, to present on several aspects. One will be a paper by Zack Struver on all of the CL bills introduced in the US Congress since the 19th Century (most of which did not pass, but of course, some did). Another will be one or two speakers on the CLs associated with injunction cases, under the eBay standard. This will probably involve Andrew Goldman plus a practitioner or academic, we have yet to identify. Amy Kapczynski from Yale and probably one more speaker on use of 28 USC 1498 cases. On the Bayh-Dole panel, I was hoping to have me, you and Jay Thomas. Mark L. Rohrbaugh if he would participate, but I'm not sure if he will want to. There is a professor at Stanford, Lisa Ouellette, who has co-authored a paper on creating a trigger for use of exclusive licenses, and we are asking if she can make it.

Obviously, KEI is looking to see more uses of compulsory licensing. But if there are people, like yourself, who make a good case in the other direction, they are welcome too. What I primarily want are people who know stuff, and make thoughtful arguments. I'm not looking for an echo chamber at this event. You obviously would add a lot to the program.

Jamie

On Tue, Dec 20, 2016 at 10:46 AM, Joe Allen <jallen@allen-assoc.com> wrote:

> I have several things up in the air right now for February. Why don't you send me more information about what you have in mind and who the other speakers will be and if I can't attend can perhaps recommend someone else.
>
> Hope you and your family have a wonderful Holiday and a Happy New Year!
>
> On 12/19/2016 3:19 PM, Jamie Love wrote:
>
> > Joe, we are rescheduling the meeting on compulsory licensing to February 24, which is also a Frida

y. Would that date for work you?

Jamie

--
James Love. Knowledge Ecology International
http://www.keionline.org/donate.html
KEI DC tel: +1.202.332.2670, US Mobile: b6 Geneva Mobile: b6
twitter.com/jamie_love

--

Joseph P. Allen
President
Allen and Associates
60704 Rt. 26, South
Bethesda, OH 43719
(W) 740-484-1814
(c) b6
www.allen-assoc.com

--
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KEI DC tel: +1.202.332.2670, US Mobile:
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twitter.com/jamie_love

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www.allen-assoc.com

<The National Cancer Institute Didn't Deserve Its Treatment in the NY Times.docx>

From: Lambertson, David (NIH/NCI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=3C95B34F709746A8A2553CE54E74ACE2-LAMBERTSOND]
Sent: 8/15/2019 1:10:53 AM
To: Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]
Subject: RE: Letter Responsive to KEI Objection for Review
Attachments: A-366-2019_Response to KEI.pdf; A-367-2019_Response to KEI.pdf

Sure thing, here are the final versions that were sent out this evening.

David A. Lambertson, Ph.D.
Senior Technology Transfer Manager
Technology Transfer Center
National Cancer Institute/NIH
david.lambertson@nih.gov
http://ttc.nci.nih.gov/

9609 Medical Center Drive, Rm 1-E530 MSC 9702
Bethesda, MD 20892-9702 (USPS)
Rockville, MD 20850-9702 (Overnight/express mail)
Phone (Main Office): 240-276-5530
Phone (direct): b6
Fax: 240-276-5504

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From: Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>
Sent: Wednesday, August 14, 2019 1:36 PM
To: Berkley, Dale (NIH/OD) [E] <berkleyd@od.nih.gov>; Lambertson, David (NIH/NCI) [E] <david.lambertson@nih.gov>
Subject: RE: Letter Responsive to KEI Objection for Review

Dave, please send me the final after it goes out.

From: Berkley, Dale (NIH/OD) [E] <berkleyd@od.nih.gov>
Sent: Wednesday, August 14, 2019 1:03 PM
To: Lambertson, David (NIH/NCI) [E] <david.lambertson@nih.gov>; Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>
Subject: RE: Letter Responsive to KEI Objection for Review

Dave:

b5

Thanks, Dale

Dale D. Berkley, Ph.D., J.D.
Office of the General Counsel, PHD, NIH Branch
Bldg. 31, Rm. 47
Bethesda, MD 20892
301-496-6043
301-402-2528(Fax)

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From: Lambertson, David (NIH/NCI) [E] <david.lambertson@nih.gov>
Sent: Wednesday, August 14, 2019 8:05 AM
To: Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>; Berkley, Dale (NIH/OD) [E] <berkleyd@od.nih.gov>
Subject: RE: Letter Responsive to KEI Objection for Review

Thanks Mark, I believe the attached is what you were suggesting. Once I hear confirmation from you and Dale that this version is acceptable, I will send the letters to KEI.

Thanks,
Dave

David A. Lambertson, Ph.D.
Senior Technology Transfer Manager
Technology Transfer Center
National Cancer Institute/NIH
david.lambertson@nih.gov
http://ttc.nci.nih.gov/

9609 Medical Center Drive, Rm 1-E530 MSC 9702
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From: Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>
Sent: Tuesday, August 13, 2019 10:43 AM
To: Lambertson, David (NIH/NCI) [E] <david.lambertson@nih.gov>; Berkley, Dale (NIH/OD) [E] <berkleyd@od.nih.gov>
Subject: RE: Letter Responsive to KEI Objection for Review

Dave:

b5

-Mark

From: Lambertson, David (NIH/NCI) [E] <david.lambertson@nih.gov>
Sent: Tuesday, August 13, 2019 10:07 AM
To: Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>; Berkley, Dale (NIH/OD) [E] <berkleyd@od.nih.gov>
Subject: Letter Responsive to KEI Objection for Review

Good morning Dale and Mark,

b5

Thanks,
Dave

David A. Lambertson, Ph.D.
Senior Technology Transfer Manager
Technology Transfer Center
National Cancer Institute/NIH
david.lambertson@nih.gov
http://ttc.nci.nih.gov/

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14 August 2019

VIA E-MAIL ONLY

James Love
Knowledge Ecology International
1621 Connecticut Ave. NW, Suite 500
Washington, DC 20009

IN RE: Prospective Grant of an Exclusive License (NIH License Application A-366-2019) to Kite Pharma, Inc., published on 12 July 2019 in *Federal Register* Vol. 84, No. 134, pages 33270

Dear Mr. Love:

Thank you for providing us with your comments regarding the notice of intent to grant a license to Kite Pharma, Inc. (Kite), by the National Cancer Institute (NCI).

Prior to posting a notice for a proposed grant of an exclusive license, the NCI determines that the criteria set forth in 37 CFR 404.7(a)(1)(ii-iii) have been satisfied and that the company is qualified both technically and financially to be granted an exclusive license to the Government's intellectual property in the fields of use as specified. The notice period provides an opportunity for public comment and possible objection to the proposed license. We consider all comments prior to negotiating the proposed license.

While your comments have been given full consideration, they do not persuade us that the grant of an exclusive license to Kite for NCI technology E-205-2018-0 in the limited field of use described in the notice would be inconsistent with the regulations and, furthermore, advance public health. With respect to your concern that the license would be anticompetitive, we determined that this was not the case prior to the publication of the notice. Specifically, and as you noted in your own objection, there is already an FDA-approved alternative (Kymriah) to any therapeutic that would arise from the proposed license, said alternative being marketed by a competitor. Furthermore, there remain fields of use available within the E-205-2018-0 technology that could be licensed by other interested parties, and products from these prospective licenses could also compete with a Kite-developed therapy. Your other questions and statements have either been addressed in many previous responses to you or are not relevant to the statutory criteria for licensing.

In conclusion, NCI has determined that your objection did not raise an issue that would preclude the grant of the proposed exclusive license, and the NCI intends to proceed with the negotiation of the license.

Sincerely,
David A. Lambertson, Ph.D.
Senior Technology Transfer Manager
National Cancer Institute, TTC
david.lambertson@nih.gov

14 August 2019

VIA E-MAIL ONLY

James Love
Knowledge Ecology International
1621 Connecticut Ave. NW, Suite 500
Washington, DC 20009

IN RE: Prospective Grant of an Exclusive License (NIH License Application A-367-2019) to Kite Pharma, Inc., published on 12 July 2019 in *Federal Register* Vol. 84, No. 134, pages 33272

Dear Mr. Love:

Thank you for providing us with your comments regarding the notice of intent to grant a license to Kite Pharma, Inc. (Kite), by the National Cancer Institute (NCI).

Prior to posting a notice for a proposed grant of an exclusive license, the NCI determines that the criteria set forth in 37 CFR 404.7(a)(1)(ii-iii) have been satisfied and that the company is qualified both technically and financially to be granted an exclusive license to the Government's intellectual property in the fields of use as specified. The notice period provides an opportunity for public comment and possible objection to the proposed license. We consider all comments prior to negotiating the proposed license.

While your comments have been given full consideration, they do not persuade us that the grant of an exclusive license to Kite for NCI technology E-205-2018-0 in the limited field of use described in the notice would be inconsistent with the regulations and, furthermore, advance public health. With respect to your concern that the license would be anticompetitive, we determined that this was not the case prior to the publication of the notice. Specifically, and as you noted in your own objection, there is already an FDA-approved alternative (Kymriah) to any therapeutic that would arise from the proposed license, said alternative being marketed by a competitor. Furthermore, there remain fields of use available within the E-205-2018-0 technology that could be licensed by other interested parties, and products from these prospective licenses could also compete with a Kite-developed therapy. Your other questions and statements have either been addressed in many previous responses to you or are not relevant to the statutory criteria for licensing.

In conclusion, NCI has determined that your objection did not raise an issue that would preclude the grant of the proposed exclusive license, and the NCI intends to proceed with the negotiation of the license.

Sincerely,
David A. Lambertson, Ph.D.
Senior Technology Transfer Manager
National Cancer Institute, TTC
david.lambertson@nih.gov

From: Myles, Renate (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/CN=RECIPIENTS/CN=MYLESR]
Sent: 1/3/2017 5:45:35 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=OD/cn=ROHRBAUM]
Subject: RE: [Ip-health] BuzzFeed News: If Taxpayers Invent A Drug, Should The Government Just Give It Away?

Yes, you came to my office and Amanda and Emma joined the call. Just back at my desk, so will read it.

-----Original Message-----
From: Rohrbaugh, Mark (NIH/OD) [E]
Sent: Tuesday, January 03, 2017 12:08 PM
To: Myles, Renate (NIH/OD) [E] <mylesr@od.nih.gov>
Subject: FW: [Ip-health] BuzzFeed News: If Taxpayers Invent A Drug, Should The Government Just Give It Away?

Do you remember my talking to them? Not sure which one that was.

Do you know if they had a FOIA as well. It seems like it.

-----Original Message-----
From: Zack Struver [mailto:zack.struver@keionline.org]
Sent: Tuesday, January 03, 2017 11:18 AM
To: Ip-health <ip-health@lists.keionline.org>
Subject: [Ip-health] BuzzFeed News: If Taxpayers Invent A Drug, Should The Government Just Give It Away?

https://www.buzzfeed.com/danvergano/nih-drug-giveaway

If Taxpayers Invent A Drug, Should The Government Just Give It Away?

When National Institutes of Health gave away a taxpayer-funded Hepatitis C drug, officials brushed aside requests to limit the price charged to consumers.

posted on Dec. 31, 2016, at 11:24 a.m.

Dan Vergano
BuzzFeed News Reporter

What if the taxpayer money invented a better treatment for hepatitis, and then just gave it away?

Officials at the National Institutes of Health said that's exactly how it's supposed to work, when queried over public records that show the federal research agency licensed out a potential new hepatitis drug while spurning calls to require the company to set "reasonable prices" for consumers.

"It would be unfortunate," an NIH official, Anna Amar, wrote in a 2015 email, if questioning of the deal by public interest groups, "bothers the company enough to reconsider the license."
In spite of the questions, the NIH completed the licensing deal with an unknown start-up called Virotas LLC in April of 2015. It was one of about 80 such cooperative research and development agreements (CRADA's) that the federal research agency signs every year.

"All we are doing is asking some reasonable questions about giving away the rights to a promising drug," James Love of public interest group Knowledge Ecology International, told BuzzFeed News. "Why would you exclusively license the rights to a promising drug to an unknown firm with no track record?"

The dispute "is not the first time someone has raised questions over NIH's method of giving exclusive rights to promising drugs," Washington University law professor Rachel Sachs told BuzzFeed News. Since the 1980's, health policy experts have asked why the NIH, the $31 billion federal powerhouse behind the US biomedical research system, doesn't claw back more money from the pharmaceutical industry, where profit margins are rivaled only by banking.

"Somebody has to put pressure on them," Sachs said. "KEI is asking the right questions here."

In the case of chlorcyclizine, National Institute of Diabetes and Digestive and Kidney Diseases researcher T. Jake Liang has shown that the forty-year old drug limits hepatitis in mice. The results showed enough promise against Hepatitis C — a virus that infects about 3 million people nationwide — that NIH funded a 50-patient safety trial of the drug, which is fairly unusual for the basic research institute. (That human trial ended in September, with results still under analysis.)

The drug's licensing last year came just as a debate over the high price of some new hepatitis drugs, notably Gilead Pharmaceuticals' $84,000 Sovaldi, attracted the eye of Congress. A Senate Finance Committee investigation last year found that Gilead employed "a calculated scheme for pricing and marketing its Hepatitis C drug based on one primary goal, maximizing revenue, regardless of the human consequences," according to Sen. Ron Wyden of Oregon.

Given such controversies, it's tone deaf at the least to exclusively license a new hepatitis drug to a small firm without any promise of reasonable prices for taxpayers, Love said. Public records released to his group in October show that within the NIH, questions were raised about a response to the reasonable price request, but were ultimately brushed off as beyond the mission of the research institute.

"We take it seriously, but it is not our mission to control drug prices," NIH technology transfer chief Mark Rohrbaugh told BuzzFeed News. Previous efforts to work price restrictions into such agreements scared away firms and ended in 1995, he said. Licensing more than tripled afterwards, with one of the best-known licensing successes, a blood vessel collar coated with a chemotherapy drug that spares patients from heart bypass surgery, coming in 2004.

"The return to taxpayers is new drugs to the public," Rohrbaugh said.

The license agreement for chlorcyclizine requires the company to pay nothing up front, committing only to pay the NIH an 8% royalty rate on any profits from the drug, with up to $150,000 going directly to the scientists who discovered it. About two dozen staff scientists collect this top number every year at NIH, although the average royalty to staffers there is only $9,000. In 2014 the NIH collected $147 million in royalties from all of its licenses, which includes medical tests and biological materials as well as drugs.

The advocacy group also requested the NIH allow outside researchers continue to look for new uses of the drug, make the research spending that Virotas does transparent to taxpayers, and allow the World Health Organization (WHO) to request a royalty-free license for NIH inventions. A WHO survey in April concluded that the newest hepatitis drugs were essentially "unaffordable" in 12 countries, such as Turkey and Egypt, where prices exceeded the average yearly income.

NIH staff vetted the firm's ability to shepherd a promising drug through the Food and Drug Administration's approval process, Rohrbaugh said. Fewer than 3 in 10 drugs that makes it as far as starting human volunteer testing runs this gantlet, where full blown trials can cost tens of millions of dollars apiece. The high cost of getting a drug approved means companies are unlikely to invest in licenses that come with price restrictions, he said.

Nevertheless, the US government retains "march in" rights on drugs to make them affordable, Annette Gaudino of the Treatment Action Group told BuzzFeed News by email. But those rights have only been used in wartime or after bioterrorism events. Refusal to intervene in the case of costly drugs, or to cut off unreasonable prices before they start with licenses, she said, raises questions about NIH's rationale for licensing drugs.

"Costs are real, but price is a choice," Gaudino said. "This gets right to the heart of what government is for: To intervene when necessary to preserve the common good, or to smooth the way for entrenched interests?"

But even if the NIH made "reasonable price" requirements a part of its drug licenses, it might not make a difference, said David Evans of Project Inform, an advocacy group for affordable HIV and hepatitis drugs.

"What we claim is the price of a drug, whether it's $84,000 or $300,000 is almost meaningless," he told BuzzFeed News. "Drug pricing in the US is so complicated," he said, because in reality there isn't really a free market for drugs, but a bewildering kaleidoscope of agreements between hospitals, insurers, clinics, and federal programs such as Medicare, all paying different discounts and rates for medicine.

Some very expensive drugs are sold at deep discount to clinics for low-income patients, Evans noted, and forcing a uniform price on them, might actually raise the price for the most vulnerable. "That makes prices a very difficult calculation for anyone to make, much less asking folks inside NIH to figure it out."

For that reason, Love suggested that NIH get out of the drug licensing business and that such deals should be handled by the Treasury Department or Medicare accountants more interested in the bottom line.

"Other countries are paying less for these drugs we paid to invent," Love said.

"There should be some limits."

--
Zack Struver, Communications and Research Associate Knowledge Ecology International
zack.struver@keionline.org
Twitter: @zstruver <https://twitter.com/zstruver>
Office: +1 (202) 332-2670 Cell: b6 keionline.org
____
Ip-health mailing list
Ip-health@lists.keionline.org
http://lists.keionline.org/mailman/listinfo/ip-health_lists.keionline.org

From: Berkley, Dale (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5EE461C29F5045A49F0ADF82CAAA2F31-BERKLEYD]
Sent: 2/14/2018 3:07:34 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]; Rogers, Karen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b23ef4ca2fa14a6eb174ee611953a396-rogersk]
Subject: RE: question regarding NIH tech transfer and 40 U.S.C. 559

b5

Best, Dale

Dale D. Berkley, Ph.D., J.D.
Office of the General Counsel, PHD, NIH Branch
Bldg. 31, Rm. 47
Bethesda, MD 20892
301-496-6043
301-402-2528(Fax)
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From: Rohrbaugh, Mark (NIH/OD) [E]
Sent: Wednesday, February 14, 2018 9:36 AM
To: Rogers, Karen (NIH/OD) [E] <rogersk@od.nih.gov>
Cc: Berkley, Dale (NIH/OD) [E] <berkleyd@od.nih.gov>
Subject: Re: question regarding NIH tech transfer and 40 U.S.C. 559

b5

Sent from my iPhone

On Feb 14, 2018, at 8:13 AM, Rogers, Karen (NIH/OD) [E] <rogersk@od.nih.gov> wrote:

> Good Morning Mark and Dale – Dave Lambertson let me know that NCI does not plan to respond to this request from KEI. They are kicking it up to us. Can you please let me know how we should address this inquiry? Regards, Karen
>
> *Karen L. Rogers*
> *Acting Director*
> *Office of Technology Transfer*
> *National Institutes of Health*
> *6011 Executive Boulevard, Suite 325*
> *Rockville, MD 20852*
> *E-Mail: RogersK@nih.gov*
> *Phone: 301-435-4359*
> *Fax: 301-402-8678*

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From: Rohrbaugh, Mark (NIH/OD) [E]
Sent: Tuesday, February 13, 2018 5:07 PM
To: Rogers, Karen (NIH/OD) [E] <rogersk@od.nih.gov>; Lambertson, David (NIH/NCI) [E] <david.lambertson@nih.gov>
Cc: Berkley, Dale (NIH/OD) [E] <berkleyd@od.nih.gov>
Subject: RE: question regarding NIH tech transfer and 40 U.S.C. 559

Good catch Karen. **b5**
b5

From: Rogers, Karen (NIH/OD) [E]
Sent: Tuesday, February 13, 2018 4:56 PM
To: Lambertson, David (NIH/NCI) [E] <david.lambertson@nih.gov>
Cc: Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>; Berkley, Dale (NIH/OD) [E] <berkleyd@od.nih.gov>
Subject: RE: question regarding NIH tech transfer and 40 U.S.C. 559

b5

I also received a phone message from KEI. I don't plan to call him back. Please let me know what you end of sending in response. Thanks, Karen

Karen L. Rogers
Acting Director
Office of Technology Transfer
National Institutes of Health
6011 Executive Boulevard, Suite 325
Rockville, MD 20852
E-Mail: RogersK@nih.gov
Phone: 301-435-4359
Fax: 301-402-8678

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From: Rohrbaugh, Mark (NIH/OD) [E]
Sent: Tuesday, February 13, 2018 1:58 PM
To: Lambertson, David (NIH/NCI) [E] <david.lambertson@nih.gov>; Berkley, Dale (NIH/OD) [E] <berkleyd@od.nih.gov>
Cc: Rogers, Karen (NIH/OD) [E] <rogersk@od.nih.gov>
Subject: RE: question regarding NIH tech transfer and 40 U.S.C. 559

b5

From: Lambertson, David (NIH/NCI) [E]
Sent: Tuesday, February 13, 2018 1:52 PM
To: Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>; Berkley, Dale (NIH/OD) [E] <berkleyd@od.nih.gov>
Cc: Rogers, Karen (NIH/OD) [E] <rogersk@od.nih.gov>
Subject: FW: question regarding NIH tech transfer and 40 U.S.C. 559

Good afternoon Mark and Dale,

Karen and I received the below e-mail from Mr. Andrew Goldman of Knowledge Ecology International. I spoke briefly with Richard, and he suggested I forward it to you both for a response.

Cheers,
Dave

David A. Lambertson, Ph.D.
Senior Technology Transfer Manager
Technology Transfer Center
National Cancer Institute/NIH
david.lambertson@nih.gov
http://ttc.nci.nih.gov/

9609 Medical Center Drive, Rm 1-E530 MSC 9702
Bethesda, MD 20892-9702 (USPS)
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Phone (direct): b6
Fax: 240-276-5504

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From: Andrew Goldman [mailto:andrew.goldman@keionline.org]
Sent: Tuesday, February 13, 2018 11:51 AM
To: Rogers, Karen (NIH/OD) [E] <rogersk@od.nih.gov>; Lambertson, David (NIH/NCI) [E] <david.lambertson@nih.gov>
Cc: Jamie Love <james.love@keionline.org>
Subject: question regarding NIH tech transfer and 40 U.S.C. 559

Dear Ms. Rogers, Mr. Lambertson:

I was hoping you could tell me whether, as required by 40 U.S.C. 559, NIH requests and obtains advice of the Attorney General with respect to antitrust laws prior to transferring patents and related rights from the NIH to private interests?

The relevant sections of 40 U.S.C. 559 are as follows:

> **§559. Advice of Attorney General with respect to antitrust law**
> [...]
> (b) Advice Required.—
> (1) In general.—An executive agency shall not dispose of property to a private interest until the agency has received the advice of the Attorney General on whether the disposal to a private interest would tend to create or maintain a situation inconsistent with antitrust law.
> (2) Exception.—This section does not apply to disposal of—
> (A) real property, if the estimated fair market value is less than $3,000,000; or
> (B) personal property (other than a patent, process, technique, or invention), if the estimated fair market value is less than $3,000,000.
> (c) Notice to Attorney General.—
> (1) In general.—An executive agency that contemplates disposing of property to a private interest shall promptly transmit notice of the proposed disposal, including probable terms and conditions, to the Attorney General.
> (2) Copy.—Except for the General Services Administration, an executive agency that transmits notice under paragraph (1) shall simultaneously transmit a copy of the notice to the Administrator of General Services.
> (d) Advice From Attorney General.—Within a reasonable time, not later than 60 days, after receipt of notice under subsection (c), the Attorney General shall advise the Administrator and any interested executive agency whether, so far as the Attorney General can determine, the proposed disposition would tend to create or maintain a situation inconsistent with antitrust law.
> (e) Request for Information.—On request from the Attorney General, the head of an executive agency shall furnish information the agency possesses that the Attorney General determines is appropriate or necessary to—
> (1) give advice required by this section; or
> (2) determine whether any other disposition or proposed disposition of surplus property violates antitrust law.

The statute's applicability to patents and related property rights is clarified in 41 CFR 102-75.270:

> **41 CFR 102-75.270 - Must antitrust laws be considered when disposing of property?**
>
> Yes, antitrust laws must be considered in any case in which there is contemplated a disposal to any private interest of -
>
> (a) Real and related personal property that has an estimated fair market value of $3 million or more; or
>
> (b) Patents, processes, techniques, or inventions, irrespective of cost.

Sincerely,

Andrew S. Goldman
Counsel, Policy and Legal Affairs

Knowledge Ecology International
andrew.goldman@keionline.org // www.twitter.com/ASG_KEI
tel.: +1.202.332.2670
www.keionline.org

From: Amar, Anna (NIH/NCI) [E] [/O=NIH/OU=NIHEXCHANGE/CN=NIAID/CN=AAMAR]
Sent: 1/3/2017 9:22:12 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=OD/cn=ROHRBAUM]
Subject: RE: [Ip-health] BuzzFeed News: If Taxpayers Invent A Drug, Should The Government Just Give It Away?

Yes: so basically in this situation, it was advertised by NIDDK as available for licensing and only Virotas was willing and able.

It was either partner with them by licensing it for development - or no development.

We might need to reiterate for the reporter that this was a compound not a drug that was licensed. The only way for the public to be able to have a FDA approved drug developed from this compound is to have a company willing to invest in the technology in order to get it through the regulatory approval process. If this is not done - NO ONE gets a new drug - at any price. NIH needs to work in partner with companies by licensing technologies because NIH is not set-up to develop the drugs alone. By working together (NIH on the research end and the company on the development end) is the only chance we have of having a new drug on the market to improve public health.

If an entity such as KEI would like to make other suggestions as to a possible partner to take this or any other compound through that process to develop a drug, we are very willing to approach the entity to see if we can partner with them. We agree with them that drug pricing is something that should be addressed - but preventing the partnering of research with development is not the way to do it. Without partnering with drug developers our technologies will simply sit on the research shelf.

-----Original Message-----
From: Rohrbaugh, Mark (NIH/OD) [E]
Sent: Tuesday, January 03, 2017 2:57 PM
To: Amar, Anna (NIH/NCI) [E] <anna.amar@nih.gov>
Subject: RE: [Ip-health] BuzzFeed News: If Taxpayers Invent A Drug, Should The Government Just Give It Away?

Thanks.

I will work with Communications to send some info back to the reporter, e.g. there was no CRADA, only a license, etc.
I had spoken with him before the story and explained why we are not involved in pricing, how we rarely have multiple parties interested in early-stage technologies, how much we invest vs company, high risk/high failure, etc.

-----Original Message-----
From: Amar, Anna (NIH/NCI) [E]
Sent: Tuesday, January 03, 2017 2:48 PM
To: Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>
Subject: RE: [Ip-health] BuzzFeed News: If Taxpayers Invent A Drug, Should The Government Just Give It Away?

Just FYI:

OTT TTS only gets NIDDK CRADAs when negotiation with the company is complete and ready for Subcommittee review - so you might not have access to them in TTS until then.

Anna

-----Original Message-----
From: Rohrbaugh, Mark (NIH/OD) [E]
Sent: Tuesday, January 03, 2017 1:28 PM
To: Amar, Anna (NIH/NCI) [E] <anna.amar@nih.gov>
Cc: Niebylski, Charles (NIH/NIDDK) [E] <niebylskicd@niddk.nih.gov>
Subject: RE: [Ip-health] BuzzFeed News: If Taxpayers Invent A Drug, Should The Government Just Give It Away?

There is nothing in TTS

-----Original Message-----
From: Amar, Anna (NIH/NCI) [E]
Sent: Tuesday, January 03, 2017 1:19 PM
To: Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>
Cc: Niebylski, Charles (NIH/NIDDK) [E] <niebylskicd@niddk.nih.gov>
Subject: RE: [Ip-health] BuzzFeed News: If Taxpayers Invent A Drug, Should The Government Just Give It Away?

I believe this was only a license and not a CRADA. It seems, from the article, that Jamie is not clear on the difference between the two.

Chuck should be able to confirm whether NIDDK is working on a CRADA with Virotas.

-----Original Message-----
From: Rohrbaugh, Mark (NIH/OD) [E]
Sent: Tuesday, January 03, 2017 1:14 PM
To: Amar, Anna (NIH/NCI) [E] <anna.amar@nih.gov>
Subject: RE: [Ip-health] BuzzFeed News: If Taxpayers Invent A Drug, Should The Government Just Give It Away?

In looking at TTS, I don't see a CRADA with this company, was/is there one or just the start up license to the NIDDK technology? [which is still pending patent and had only been tested in vitro, no animal data].

-----Original Message-----
From: Amar, Anna (NIH/NCI) [E]
Sent: Tuesday, January 03, 2017 11:59 AM
To: Lambert, Richard (NIH/NIAID) [C] <lambertr@niaid.nih.gov>; Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>
Cc: Mowatt, Michael (NIH/NIAID) [E] <MMOWATT@niaid.nih.gov>
Subject: RE: [Ip-health] BuzzFeed News: If Taxpayers Invent A Drug, Should The Government Just Give It Away?

Wow - I don't even know if I said it that way!!

I wonder how it ended up there? FOIA?

Mark: are your "statements" accurate?

Should there be a response to this BussFeed Article?

-----Original Message-----
From: Lambert, Richard (NIH/NIAID) [C]
Sent: Tuesday, January 03, 2017 11:35 AM
To: Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>; Mowatt, Michael (NIH/NIAID) [E] <MMOWATT@niaid.nih.gov>; Amar, Anna (NIH/NCI) [E] <anna.amar@nih.gov>
Subject: FW: [Ip-health] BuzzFeed News: If Taxpayers Invent A Drug, Should The Government Just Give It Away?

FYI

Richard A. Lambert
Contractor
National Institute of Allergy and Infectious Diseases National Institutes of Health U.S. Department of Health and Human Services
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Bethesda, MD 20892-9804
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301.496.2644 main officeline
b6 direct line
FAX 240.627.3117
lambertr@niaid.nih.gov
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-----Original Message-----
From: Zack Struver [mailto:zack.struver@keionline.org]
Sent: Tuesday, January 03, 2017 11:18 AM
To: Ip-health <ip-health@lists.keionline.org>
Subject: [Ip-health] BuzzFeed News: If Taxpayers Invent A Drug, Should The Government Just Give It Away?

https://www.buzzfeed.com/danvergano/nih-drug-giveaway

If Taxpayers Invent A Drug, Should The Government Just Give It Away?

When National Institutes of Health gave away a taxpayer-funded Hepatitis C drug, officials brushed aside requests to limit the price charged to consumers.

posted on Dec. 31, 2016, at 11:24 a.m.

Dan Vergano
BuzzFeed News Reporter

What if the taxpayer money invented a better treatment for hepatitis, and then just gave it away?

Officials at the National Institutes of Health said that's exactly how it's supposed to work, when queried over public records that show the federal research agency licensed out a potential new hepatitis drug while spurning calls to require the company to set "reasonable prices" for consumers.

"It would be unfortunate," an NIH official, Anna Amar, wrote in a 2015 email, if questioning of the deal by public interest groups, "bothers the company enough to reconsider the license."
In spite of the questions, the NIH completed the licensing deal with an unknown start-up called Virotas LLC in April of 2015. It was one of about
80 such cooperative research and development agreements (CRADA's) that the federal research agency signs every year.

"All we are doing is asking some reasonable questions about giving away the rights to a promising drug," James Love of public interest group Knowledge Ecology International, told BuzzFeed News. "Why would you exclusively license the rights to a promising drug to an unknown firm with no track record?"

The dispute "is not the first time someone has raised questions over NIH's method of giving exclusive rights to promising drugs," Washington University law professor Rachel Sachs told BuzzFeed News. Since the 1980's, health policy experts have asked why the NIH, the $31 billion federal powerhouse behind the US biomedical research system, doesn't claw back more money from the pharmaceutical industry, where profit margins are rivaled only by banking.

"Somebody has to put pressure on them," Sachs said. "KEI is asking the right questions here."

In the case of chlorcyclizine, National Institute of Diabetes and Digestive and Kidney Diseases researcher T. Jake Liang has shown that the forty-year old drug limits hepatitis in mice. The results showed enough promise against Hepatitis C — a virus that infects about 3 million people nationwide — that NIH funded a 50-patient safety trial of the drug, which is fairly unusual for the basic research institute. (That human trial ended in September, with results still under analysis.)

The drug's licensing last year came just as a debate over the high price of some new hepatitis drugs, notably Gilead Pharmaceuticals' $84,000 Sovaldi, attracted the eye of Congress. A Senate Finance Committee investigation last year found that Gilead employed "a calculated scheme for pricing and marketing its Hepatitis C drug based on one primary goal, maximizing revenue, regardless of the human consequences," according to Sen. Ron Wyden of Oregon.

Given such controversies, it's tone deaf at the least to exclusively license a new hepatitis drug to a small firm without any promise of reasonable prices for taxpayers, Love said. Public records released to his group in October show that within the NIH, questions were raised about a response to the reasonable price request, but were ultimately brushed off as beyond the mission of the research institute.

"We take it seriously, but it is not our mission to control drug prices,"
NIH technology transfer chief Mark Rohrbaugh told BuzzFeed News. Previous efforts to work price restrictions into such agreements scared away firms and ended in 1995, he said. Licensing more than tripled afterwards, with one of the best-known licensing successes, a blood vessel collar coated with a chemotherapy drug that spares patients from heart bypass surgery, coming in 2004.

"The return to taxpayers is new drugs to the public," Rohrbaugh said.

The license agreement for chlorcyclizine requires the company to pay nothing up front, committing only to pay the NIH an 8% royalty rate on any profits from the drug, with up to $150,000 going directly to the scientists who discovered it. About two dozen staff scientists collect this top number every year at NIH, although the average royalty to staffers there is only $9,000. In 2014 the NIH collected $147 million in royalties from all of its licenses, which includes medical tests and biological materials as well as drugs.

The advocacy group also requested the NIH allow outside researchers continue to look for new uses of the drug, make the research spending that Virotas does transparent to taxpayers, and allow the World Health Organization (WHO) to request a royalty-free license for NIH inventions. A WHO survey in April concluded that the newest hepatitis drugs were essentially "unaffordable" in 12 countries, such as Turkey and Egypt, where prices exceeded the average yearly income.

NIH staff vetted the firm's ability to shepherd a promising drug through the Food and Drug Administration's approval process, Rohrbaugh said. Fewer than 3 in 10 drugs that makes it as far as starting human volunteer testing runs this gantlet, where full blown trials can cost tens of millions of dollars apiece. The high cost of getting a drug approved means companies are unlikely to invest in licenses that come with price restrictions, he said.
Nevertheless, the US government retains "march in" rights on drugs to make them affordable, Annette Gaudino of the Treatment Action Group told BuzzFeed News by email. But those rights have only been used in wartime or after bioterrorism events. Refusal to intervene in the case of costly drugs, or to cut off

unreasonable prices before they start with licenses, she said, raises questions about NIH's rationale for licensing drugs.

"Costs are real, but price is a choice," Gaudino said. "This gets right to the heart of what government is for: To intervene when necessary to preserve the common good, or to smooth the way for entrenched interests?"

But even if the NIH made "reasonable price" requirements a part of its drug licenses, it might not make a difference, said David Evans of Project Inform, an advocacy group for affordable HIV and hepatitis drugs.

"What we claim is the price of a drug, whether it's $84,000 or $300,000 is almost meaningless," he told BuzzFeed News. "Drug pricing in the US is so complicated," he said, because in reality there isn't really a free market for drugs, but a bewildering kaleidoscope of agreements between hospitals, insurers, clinics, and federal programs such as Medicare, all paying different discounts and rates for medicine.

Some very expensive drugs are sold at deep discount to clinics for low-income patients, Evans noted, and forcing a uniform price on them, might actually raise the price for the most vulnerable. "That makes prices a very difficult calculation for anyone to make, much less asking folks inside NIH to figure it out."

For that reason, Love suggested that NIH get out of the drug licensing business and that such deals should be handled by the Treasury Department or Medicare accountants more interested in the bottom line. "Other countries are paying less for these drugs we paid to invent," Love said.
"There should be some limits."

--
Zack Struver, Communications and Research Associate Knowledge Ecology International
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Office: +1 (202) 332-2670 Cell: b6 keionline.org

Ip-health mailing list
Ip-health@lists.keionline.org
http://lists.keionline.org/mailman/listinfo/ip-health_lists.keionline.org

From: Myles, Renate (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/CN=RECIPIENTS/CN=MYLESR]
Sent: 4/20/2017 2:48:54 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=OD/cn=ROHRBAUM]
Subject: RE: Testing Trump: Advocates urge action over pricey cancer drug

So Ed covered this extensively last year and our position is included (see highlighted section). I think this is more about the advocacy group pushing their position to the Trump administration.

From: Rohrbaugh, Mark (NIH/OD) [E]
Sent: Thursday, April 20, 2017 10:44 AM
To: Myles, Renate (NIH/OD) [E] <mylesr@od.nih.gov>
Subject: FW: Testing Trump: Advocates urge action over pricey cancer drug

Why are they only presenting one side of the argument?

From: Berkson, Laura (NIH/OD) [E]
Sent: Thursday, April 20, 2017 9:11 AM
To: Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>
Cc: Culhane, Ned (NIH/OD) [E] <culhanee@mail.nih.gov>
Subject: Testing Trump: Advocates urge action over pricey cancer drug

I wanted to flag this article in STAT+ about march-in, which was also in the clips this morning. It includes a link to a letter KEI sent to Secretary Price and Secretary Mattis yesterday (it cc'd Dr. Collins) asking the administration to re-evaluate the Xtandi request or put it in the hands of a neutral party. Mark – you are quoted in the letter.

FROM THE CLIPS:
ADVOCATES URGE ACTION OVER PRICEY CANCER DRUG. STAT (4/19, Silverman) reports that the consumer group Knowledge Ecology International is asking the Trump Administration to assert so-called march-in rights on the prostate cancer treatment Xtandi, which is marketed by Astellas Pharma at a wholesale cost of $129,000 per year. The group said in a letter that the drug was developed with grants from the National Institutes of Health and the Department of Defense by the University of California, Los Angeles, which went on to license the treatment. STAT says that the group first asked the Obama Administration to use march-in rights on the drug, but it "is betting its effort will have a greater chance of appealing to President Trump."

FULL ARTICLE:

Testing Trump: Advocates urge action over pricey cancer drug

By ED SILVERMAN | APRIL 19, 2017

After being rebuffed by the Obama administration, a consumer advocacy group is now asking the Trump administration to use federal law to widen access in the United States to a pricey prostate cancer drug that was developed with taxpayer funds.

The consumer group, Knowledge Ecology International, is betting its effort will have a greater chance of appealing to President Trump, who has criticized drug makers over their pricing, an issue that the Obama administration did relatively little to address. The Obama administration, in fact, had previously rejected a petition to widen access to the drug, which is known as Xtandi.

At issue is the cost of the drug, which is sold by Astellas Pharma and has a wholesale price of $129,000, or about two to four times more than what other high-income countries are paying, according to KEI, which tracks intellectual property and access to medicines issues. The group notes Medicare paid more than $790 million in 2015, up from $447 million in 2014, and argued the price led to high co-payments.

The group also noted that the drug was developed at the University of California, Los Angeles, with grants from the National Institutes of Health and the Department of Defense. One of the chief inventors of the drug was a professor at UCLA, which then licensed the drug to Medivation. That company, which was later acquired by Pfizer, struck a marketing deal with Astellas.

"In short, does the Trump administration support a policy that Americans will pay more than patients in any other country on the planet for a medicine that was created with American tax dollars?" the consumer group wrote in a letter on Wednesday to Secretary of Health and Human Services Tom Price and Secretary of Defense Jim Mattis.

"President Trump could take decisive action to address the problem of high drug prices in this instance by instructing the government to use its authority," the letter continued. "… This case continues to have merit and tremendous significance in the urgent fight against out-of-control drug prices. We believe that the Obama administration made a mistake in not acting. And we believe that the Trump administration has an opportunity to rectify that mistake and to take bold action here for the benefit of patients, consumers, and taxpayers."

The consumer group argued the NIH has the ability to issue so-called march-in rights, which refer to overriding a patent. Under federal law, this allows an agency that funds private research to require a drug maker to license its patent to another party in order to "alleviate health and safety needs which are not being reasonably satisfied" or when the benefits of a drug are not available on "reasonable terms."

Last year, the NIH denied a petition that was filed by KEI and Union for Affordable Cancer Treatment, another advocacy group, because there was no information to suggest that Xtandi is or will be in short supply. The agency, which has rarely granted such petitions, noted that the litmus test used in one previous case was whether there were sufficient supplies of the medicine for which a petition was sought.

In its letter, however, KEI noted that it "never argued that shortage of supply was the issue; the issue was then and remains now that a Japanese corporation is charging Americans an excessive amount, far more than anywhere else in the world, to the detriment of American patients and taxpayers. The rejection thus failed to contend with a central point of the petition — that the excessive, discriminatory prices of Xtandi are unreasonable."

At the same time, the group is urging the administration to grant so-called royalty rights to a company, other than the Xtandi manufacturer, that could then make a generic version for sale in poor nations. These rights are a separate provision under federal law that the government may use at any time and for any reason on federally funded inventions. However, the NIH Director Francis Collins also rejected this request.

We asked Astellas for comment and will update you accordingly. Meanwhile, we will reiterate a statement that was provided to us last June, when the company was asked about the matter:

"Astellas is focused on delivering innovative medicines that address the unmet medical needs of the patients we serve around the world. We are pleased that the National Institutes of Health has concluded that Xtandi is broadly available to patients, and we are committed to continuing our work with our diverse stakeholders to provide patients with affordable access to our medicines."

From: Plude, Denise (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/CN=RECIPIENTS/CN=PARKSDE]
Sent: 4/26/2016 5:19:33 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=OD/cn=ROHRBAUM]
Subject: WF 346098 - Response due 5/11
Attachments: email.pdf; incoming.pdf

Work Folder Information
Work Folder: WF 346098
Process: Response Creation
Program Analyst: Marshall, Lisa (NIH/OD) [E]
Due Date: May 11, 2016
WF Subject: Asks Dr. Collins to hold a public health hearing on the request that the NIH use its march-in rights in patents related to the prostate cancer drug, Xtandi (enzalutamide).
IC: od_osp
From: Nader, Ralph
To: Collins, Francis
Remarks: Assigned to OSP to work with OER to prepare a response for Dr. Collins' signature. Please provide draft response to Exec Sec by COB, Wednesday, May 11. Thanks very much, Lisa Marshall

From: Evan West
Sent:22 Apr 2016 17:37:58 -0400
To: Collins, Francis (NIH/OD) [E]
Subject: Letter from Ralph Nader
Attachments:RN-LettertoFrancisCollins-22April2016.pdf

Hello Director Collins,

Attached please find a letter from Ralph Nader that was also sent to your office my post this afternoon.

Best regards,

--
Evan West

Assistant to Ralph Nader
Center for Study of Responsive Law
www.csrl.org
(202) 387-8030

22 April 2016

Francis Collins, M.D., Ph.D.
Director
National Institutes of Health
9000 Rockville Pike
Bethesda, MD 20892
Via: Francis.Collins@nih.hhs.gov

Dear Director Collins:

I write to you to ask that you hold a public health hearing on the request that the NIH use its royalty free or march-in rights in patents related to the prostate cancer drug enzalutamide. The drug was invented at UCLA on grants from the NIH and the U.S. Army. Astellas, a Japanese company that has licensed the patents, is charging U.S. residents $129,000 per year, a price which is both excessive in its own right, and 2.5 to 4 times the amount that the company charges in other high income countries.

The letter from the Union for Affordable Cancer Treatment (UACT) and Knowledge Ecology International (KEI) has been supported by a dozen other consumer rights organizations as well as six U.S. Senators and six members of the U.S. House of Representatives. The issues raised in the letter involve important questions of public policy. The NIH should welcome and not avoid a more public conversation before rendering an opinion.

The fact that the NIH has failed to approve a march-in petition even once in the more than 35 years since the passage of the federal Bayh-Dole Act, and held only a single hearing on a request, is troubling. The Bayh-Dole is extremely generous in giving universities, individuals, and for-profit organizations rights to commercialize inventions funded by the NIH. In return, the Bayh-Dole Act provided safeguards, to protect the public from unreasonable use of the inventions (35 USC 200). These safeguards, spelled out in sections 201, 203, and 209 of the Act, are there to ensure that during the commercialization of the inventions, the unrestrained drive to maximize profits is not the only guiding principle for the use of the inventions.

If the NIH refuses to even hold a hearing on this request, it sends the signal that there are no boundaries when it comes to discriminating against and terribly exploiting U.S. residents, for NIH funded inventions. A refusal to even hold a hearing sends the signal to taxpayers that the NIH is unwilling to hold patent holders accountable to the statutory standard that requires that inventions are available to the public on reasonable terms, and will not use its rights in the patents when the unreasonable terms involve price gouging and price discrimination that harms U.S. residents.

Unconstrained greed and self interest are not a value that a public institution such as the NIH should so endemically endorse, and in the long run, evidence that public resources are being misused undermines support for public institutions, including the NIH, which can play such a visible role in advancing the public interest. We have been at conferences where you have discussed the compatibility of compassionate values, rooted in faith and scientific endeavors. Very applicable here.

Sincerely,

Ralph Nader

Ralph Nader

From: Joe Allen [jallen@allen-assoc.com]
Sent: 4/20/2017 1:47:28 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=OD/cn=ROHRBAUM]; Hammersla, Ann (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=Recipients/cn=hammerslaa]
Subject: KEI petitions HHS/ DOD (again) for Xtandi march in
Attachments: KEI petition on Xtandi to Trump DOD.pdf

Just sent yesterday. See attached

--

Joseph P. Allen
President
Allen and Associates
60704 Rt. 26, South
Bethesda, OH 43719
(W) 740-484-1814
(c) b6
www.allen-assoc.com

KEI
KNOWLEDGE ECOLOGY INTERNATIONAL

UACT
UNION FOR AFFORDABLE CANCER TREATMENT

April 19, 2017

The Honorable Tom Price, M.D.
Secretary
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201
Via: Thomas.Price@hhs.gov

The Honorable Jim Mattis
Secretary
Department of Defense
1400 Defense Pentagon
Washington, D.C. 20301-1400
Via: whs.pentagon.esd.mbx.cmd-correspondence@mail.mil

Dear Secretaries Price and Mattis:

Knowledge Ecology International (KEI) is a non-profit organization with offices in Washington, DC. The Union for Affordable Cancer Treatment (UACT) is a non-profit cancer patient group. More about each group is available on their respective web pages: http://keionline.org and http://cancerunion.org.

This letter is to request that the United States Government reconsider the decision of the Obama Administration to deny our petition, initially filed in January 2016, that the government use its rights in patents under the Bayh Dole Act (35 U.S.C. §§ 200 *et seq.*) for the excessively-priced, blockbuster drug enzalutamide (marketed by Astellas Pharma as Xtandi). The initial petition highlighted the possibility of using either march-in rights under 35 U.S.C. § 203, or the royalty-free rights in the patents under 35 U.S.C. § 202(c)(4), in order to allow for generic competition and more affordable prices. The petition is attached.

The failure to act on behalf of the American people in this case was a deliberate choice made by the previous administration, to accept an outcome that has U.S. residents paying far more than any other country for a drug invented with taxpayer funding.

Given the Trump Administration's promise to make great deals for American citizens, we believe that this case is well-suited to review with new attention. In short, does the Trump administration support a policy that Americans will pay more than patients in any other country on the planet for a medicine that was created with American tax dollars?

In the initial petition, HHS was urged to act to permit competition in the supply of the drug when the prices in the United States were higher than the median prices of countries with comparable incomes and large economies.

Moreover, in addition to the policy that the U.S. should not pay higher prices than other high income countries, the HHS should also have a policy to address the cases where high prices outside of the United States present access barriers, for example, in developing countries where prices are excessive and incomes are low.

The KEI/UACT Xtandi Petition

The 26-page KEI/UACT petition focused on the fact that Astellas Pharma, a Japanese corporation, is currently charging American citizens more than $130,000 per patient per year for Xtandi, an effective and important medicine for prostate cancer. That price is more than any other country in the world, and three to four times the price charged in other high-income industrialized countries, including Japan. The excessive price is in spite of the fact that the drug was developed using U.S. taxpayer money via grants from the National Institutes of Health (NIH) and the Department of Defense.

We also noted that the cost of Xtandi to Medicare has ballooned in recent years, up from $34.9 million in 2012 to over $447 million in 2014. In 2015, Medicare paid a total of over $790 million for Xtandi, representing 69% of U.S. sales and 41% of global sales for the drug. Sales of Xtandi are projected to increase substantially in the coming years.

Finally, we argued that those high prices have resulted in high copayments and limited access for patients in the United States, including those who receive prescription drug benefits through Medicare.[1]

The KEI/UACT petition drew a significant amount of attention and support, including: a bicameral letter of support from six members of the House of Representatives and six members of the Senate; a letter of support from over fifty international non-governmental organizations; and many articles in a wide variety of media publications.[2]

In June 2016, Director Collins rejected the KEI/UACT petition in a two-page letter, failing to address the argument regarding high prices, and instead grounding the rejection on the absence of evidence of shortage of supply. He stated that the petition "provides no information and no information was provided from public sources to suggest that enzalutamide is currently or will be in short supply."

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[1] See: http://keionline.org/node/2485.

[2] For a comprehensive set of materials and documents relating to the KEI/UACT petition, see http://keionline.org/xtandi.

KEI/UACT never argued that shortage of supply was the issue; the issue was then and remains now that a Japanese corporation is charging Americans an excessive amount, far more than anywhere else in the world, to the detriment of American patients and taxpayers. The rejection thus failed to contend with a central point of the petition — that the excessive, discriminatory prices of Xtandi are unreasonable. Director Collins also neglected to explain why the federal government should not use the royalty-free rights in the patents to address the pricing abuses. The royalty free rights are a separate provision under the Bayh Dole Act that the government may use at any time, for any reason, and without precondition, on federally-funded inventions.

KEI filed comments with the Department of the Army in a separate proceeding that are germane to this issue, and are attached here for consideration with the Xtandi petition.[3] In those comments, KEI addressed the statutory phrase "practical application," defined under 35 U.S.C. § 201(f) to include "available to the public on reasonable terms," including a discussion of the contradictory statements made by Senators Birch and Dole during their post-Senate careers on the relationship between the term "available to the public on reasonable terms" and the price the public pays. This attached submission also provided examples where the term "reasonable terms" was interpreted to include price.

Revisiting the Petition under the Trump Administration

President Trump has rightfully spoken many times about the problem of outrageous drug prices, both during his campaign and after. In January 2017, President Trump stated that the pharmaceutical industry was "getting away with murder,"[4] and in his address to Congress again focused on the problem of high drug prices and his intent to "bring them down immediately."[5]

President Trump's statements echo the sentiments of a broad bipartisan consensus across the country. In a widely reported public opinion poll from October 2016, 74 percent of the American public viewed making high-cost drugs for chronic conditions affordable as a top priority for the incoming administration and Congress, and a majority of the public likewise said that government action to lower prescription drug prices was a top priority.[6]

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[3] KEI's comments can also be viewed here: http://keionline.org/sites/default/files/KEI-March_10_2017-3rd-Comments-Zika.pdf.

[4] http://www.reuters.com/article/us-usa-trump-drugpricing-idUSKBN14V24J

[5] http://thehill.com/policy/healthcare/321706-trump-to-congress-we-must-bring-down-drug-prices-immediately

[6] http://kff.org/health-costs/poll-finding/kaiser-health-tracking-poll-october-2016/

President Trump could take decisive action to address the problem of high drug prices in this instance by instructing the government to use its authority in this case under the existing Bayh Dole law.

Review of the Xtandi Petition Should Be Undertaken By An Impartial Office

If the government does proceed in reevaluating the Xtandi request, we ask that the Administration place this decision in the hands of a neutral party who does not have an established and documented predisposition against the use of government rights under Bayh Dole. It is clear from numerous statements by NIH officials, including Dr. Mark Rohrbaugh, a Special Advisor for Technology Transfer and the former head of the NIH's Office of Technology Transfer, and Director Francis Collins, that the decision on this issue should not rest with them. In December 2016, Mr. Rohrbaugh stated on several occasions that "it is not our mission to control drug prices,"[7] and that, "N.I.H. has made it clear that its job is not to decide prices of drugs, period."[8]

Similarly, Director Collins responded to questions by Senator Durbin at a hearing of the Senate Labor-HHS appropriations subcommittee on April 7, 2016 by stating that he did not believe that march-in rights under the Bayh Dole Act were intended to address problems of price but rather to address problems of access, and that he was concerned "about the negatives that may flow forward, if we use march-in rights in a very broad way about drug pricing."[9] To this, Senator Durbin responded that problems of access go beyond physical accessibility, saying, "if a drug is overpriced, it is not accessable."

Conclusion

KEI and UACT believe, along with many others, that this case continues to have merit and tremendous significance in the urgent fight against out-of-control drug prices. We believe that the Obama Administration made a mistake in not acting. And, we believe that the Trump Administration has an opportunity to rectify that mistake, and to take bold action here for the benefit of patients, consumers, and taxpayers.

We request a meeting to discuss this matter in further detail.

Sincerely,

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[7] https://www.buzzfeed.com/danvergano/nih-drug-giveaway

[8] https://www.nytimes.com/2016/12/19/health/harnessing-the-us-taxpayer-to-fight-cancer-and-make-profits.html?_r=0

[9] Video of this exchange is available here: https://www.youtube.com/watch?v=wpo5sOQV9HY

Andrew S. Goldman
Counsel, Policy & Legal Affairs
Knowledge Ecology International
202-332-2670
andrew.goldman@keionline.org

Cc: Francis Collins, M.D., Ph.D.
Director
National Institutes of Health
9000 Rockville Pike
Bethesda, MD 20892
Via: Francis.Collins@nih.hhs.gov

From: Lambert, Richard (NIH/NIAID) [C] [/O=NIH/OU=NIHEXCHANGE/CN=NIAID/CN=LAMBERTR]
Sent: 1/3/2017 5:14:29 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=OD/cn=ROHRBAUM]
Subject: FW: [Ip-health] NIH grant for "Development of an Intellectual Property (IP) Strategy for the Commercial Advancement of a Direct Phase II SBIR-Funded technology

FYI Another message from Jamie

Richard A. Lambert
Contractor
National Institute of Allergy and Infectious Diseases
National Institutes of Health
U.S. Department of Health and Human Services
5601 Fishers Lane, Rm. 2G47, MSC 9804
Bethesda, MD 20892-9804
(Courier: Rockville, MD. 20852)
301.496.2644 main officeline
b6 direct line
FAX 240.627.3117
lambertr@niaid.nih.gov
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-----Original Message-----
From: Jamie Love [mailto:james.love@keionline.org]
Sent: Tuesday, January 03, 2017 12:01 PM
To: Ip-health <ip-health@lists.keionline.org>
Subject: [Ip-health] NIH grant for "Development of an Intellectual Property (IP) Strategy for the Commercial Advancement of a Direct Phase II SBIR-Funded technology

https://projectreporter.nih.gov/project_info_description.cfm?aid=9253581&icde=32443948

Apparently the NIH will give you a grant to help you patent the heck out of a technology where they are also funding the research.

Project Number: 1SB1HL137591-01
Former Number: 2SB1HL131050-03
Contact PI / Project Leader: KARLSSON, SVEN M

Title: DEVELOPMENT OF AN INTELLECTUAL PROPERTY (IP) STRATEGY FOR THE COMMERCIAL ADVANCEMENT OF A DIRECT PHASE II SBIR-FUNDED HUMAN PLATELET BIOREACTOR Awardee Organization: PLATELET BIOGENESIS, INC.

PROJECT SUMMARY/ABSTRACT

Platelet BioGenesis is developing a microfluidic bioreactor to produce human platelets at clinical scale. Platelets are the 'band-aids' of the bloodstream, responsible for clot formation and blood vessel repair. Low platelet count is a significant consequence of cancer treatment, transplant, and surgery, for which plate- lets are a critical first-line therapy to prevent mortality due to uncontrolled bleeding. Platelets are
de- rived exclusively from volunteer donors. Risk of bacterial growth during room temperature storage limits plate- let shelf life to 5 days, 2 of which are expended by bacterial screening, and 1 during transport to hospitals. As a result blood centers typically do not have more than a 1.5-day platelet inventory available for transfu- sion, making platelet unit inventory especially vulnerable to routine depletion[1, 2]. To address this ma- jor unmet need we are developing a platelet bioreactor that reproduces key features of adult bone marrow (physiological
microenvironment) to trigger platelet production from human induced pluripotent stem cells (hiP- SCs, a replenishable source of progenitor cells which can be stored frozen for years) at clinical/commercial scale.
This SBIR CRP Program proposal for Technical Assistance (SB1) outlines a comprehensive intellectual property strategy for Platelet BioGenesis to develop a proprietary, patent protected technology to produce cGMP-compliant human bioreactor-derived platelets at commercial scale for clinical use in 3 specific aims: Aim 1. Understanding the Patent Landscape.
We will work with IP counsel to: (1) identify and assess licens- ing various third party patents and patent applications related to megakaryocyte differentiation protocols and the platelet bioreactor, (2)

perform further patent searches (landscape and/or freedom to operate) to ensure that we are able to commercialize our technology without infringement, and/or (3) identify any additional third party patents that may be licensed by us to further improve our competitive commercial position. Aim 2. Protecting Proprietary Technology to Enable Commercialization. We will work with IP counsel to identify intellectual property generated by us and will formulate a strategy for protecting such intellectual prop- erty, either by filing patent applications or ensuring that the technology is maintained as a trade secret. Aim 3. IP Agreements.

We will work with the IP counsel to: (1) review our non-disclosure agreements, em- ployment or consultant agreements to ensure the ownership and protection of our intellectual property, and (2) negotiate and enter into license agreements with cGMP-compliant hiPSC suppliers for access to relevant cell lines. cGMP-hiPSC line master banks will be maintained and differentiated into megakaryocytes under established supply agreements using proprietary cell culture protocols.

Public Health Relevance Statement:

PROJECT NARRATIVE Human platelets are presently derived exclusively from volunteer donors and have a shelf life of 5 days, mak- ing platelet unit inventory sensitive to depletion and putting platelet recipients at risk of sepsis and viruses dur- ing surgery, pregnancy and birth, cancer/HIV/burn-treatment, and transplant. There are currently no licensed therapeutics that immediately increase platelet counts, and insufficient platelet supply to meet projected US demand (~2.3M platelet units/year in 2013). Platelet BioGenesis has: identified cGMP-compliant hiPSC lines, validated megakaryocyte differentiation protocol and platelet storage-permissive media, and established a mi- crofluidic bioreactor to rapidly trigger functional platelet production at clinical/commercial scale. We now seek to develop a comprehensive IP strategy for linking these key technologies, which is necessary to advance bio- reactor-derived platelets (bdPLTs) for clinical use.

--
James Love. Knowledge Ecology International http://www.keionline.org/donate.html
KEI DC tel: +1.202.332.2670, US Mobile: b6, Geneva Mobile: b6, twitter.com/jamie_love

---

Ip-health mailing list
Ip-health@lists.keionline.org
http://lists.keionline.org/mailman/listinfo/ip-health_lists.keionline.org

From: Amar, Anna (NIH/NCI) [E] [/O=NIH/OU=NIHEXCHANGE/CN=NIAID/CN=AAMAR]
Sent: 1/3/2017 4:58:42 PM
To: Lambert, Richard (NIH/NIAID) [C] [/O=NIH/OU=NIHEXCHANGE/cn=NIAID/cn=LAMBERTR]; Rohrbaugh, Mark (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=OD/cn=ROHRBAUM]
CC: Mowatt, Michael (NIH/NIAID) [E] [/O=NIH/OU=NIHEXCHANGE/cn=NIAID/cn=MMOWATT]
Subject: RE: [Ip-health] BuzzFeed News: If Taxpayers Invent A Drug, Should The Government Just Give It Away?

Wow - I don't even know if I said that!!

I wonder how it ended up there? FOIA?

Mark: are your "statements" accurate?

Should there be a response to this BussFeed Article?

-----Original Message-----
From: Lambert, Richard (NIH/NIAID) [C]
Sent: Tuesday, January 03, 2017 11:35 AM
To: Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>; Mowatt, Michael (NIH/NIAID) [E] <MMOWATT@niaid.nih.gov>; Amar, Anna (NIH/NCI) [E] <anna.amar@nih.gov>
Subject: FW: [Ip-health] BuzzFeed News: If Taxpayers Invent A Drug, Should The Government Just Give It Away?

FYI

Richard A. Lambert
Contractor
National Institute of Allergy and Infectious Diseases National Institutes of Health U.S. Department of Health and Human Services
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-----Original Message-----
From: Zack Struver [mailto:zack.struver@keionline.org]
Sent: Tuesday, January 03, 2017 11:18 AM
To: Ip-health <ip-health@lists.keionline.org>
Subject: [Ip-health] BuzzFeed News: If Taxpayers Invent A Drug, Should The Government Just Give It Away?

https://www.buzzfeed.com/danvergano/nih-drug-giveaway

If Taxpayers Invent A Drug, Should The Government Just Give It Away?

When National Institutes of Health gave away a taxpayer-funded Hepatitis C drug, officials brushed aside requests to limit the price charged to consumers.

posted on Dec. 31, 2016, at 11:24 a.m.

Dan Vergano
BuzzFeed News Reporter

What if the taxpayer money invented a better treatment for hepatitis, and then just gave it away?

Officials at the National Institutes of Health said that’s exactly how it’s supposed to work, when queried over public records that show the federal research agency licensed out a potential new hepatitis drug while spurning calls to require the company to set “reasonable prices” for consumers.

“It would be unfortunate,” an NIH official, Anna Amar, wrote in a 2015 email, if questioning of the deal by public interest groups, “bothers the company enough to reconsider the license.”
In spite of the questions, the NIH completed the licensing deal with an unknown start-up called Virotas LLC in April of 2015. It was one of about

80 such cooperative research and development agreements (CRADA's) that the federal research agency signs every year.

"All we are doing is asking some reasonable questions about giving away the rights to a promising drug," James Love of public interest group Knowledge Ecology International, told BuzzFeed News. "Why would you exclusively license the rights to a promising drug to an unknown firm with no track record?"

The dispute "is not the first time someone has raised questions over NIH's method of giving exclusive rights to promising drugs," Washington University law professor Rachel Sachs told BuzzFeed News. Since the 1980's, health policy experts have asked why the NIH, the $31 billion federal powerhouse behind the US biomedical research system, doesn't claw back more money from the pharmaceutical industry, where profit margins are rivaled only by banking.

"Somebody has to put pressure on them," Sachs said. "KEI is asking the right questions here."

In the case of chlorcyclizine, National Institute of Diabetes and Digestive and Kidney Diseases researcher T. Jake Liang has shown that the forty-year old drug limits hepatitis in mice. The results showed enough promise against Hepatitis C – a virus that infects about 3 million people nationwide – that NIH funded a 50-patient safety trial of the drug, which is fairly unusual for the basic research institute. (That human trial ended in September, with results still under analysis.)

The drug's licensing last year came just as a debate over the high price of some new hepatitis drugs, notably Gilead Pharmaceuticals' $84,000 Sovaldi, attracted the eye of Congress. A Senate Finance Committee investigation last year found that Gilead employed "a calculated scheme for pricing and marketing its Hepatitis C drug based on one primary goal, maximizing revenue, regardless of the human consequences," according to Sen. Ron Wyden of Oregon.

Given such controversies, it's tone deaf at the least to exclusively license a new hepatitis drug to a small firm without any promise of reasonable prices for taxpayers, Love said. Public records released to his group in October show that within the NIH, questions were raised about a response to the reasonable price request, but were ultimately brushed off as beyond the mission of the research institute.

"We take it seriously, but it is not our mission to control drug prices,"
NIH technology transfer chief Mark Rohrbaugh told BuzzFeed News. Previous efforts to work price restrictions into such agreements scared away firms and ended in 1995, he said. Licensing more than tripled afterwards, with one of the best-known licensing successes, a blood vessel collar coated with a chemotherapy drug that spares patients from heart bypass surgery, coming in 2004.

"The return to taxpayers is new drugs to the public," Rohrbaugh said.

The license agreement for chlorcyclizine requires the company to pay nothing up front, committing only to pay the NIH an 8% royalty rate on any profits from the drug, with up to $150,000 going directly to the scientists who discovered it. About two dozen staff scientists collect this top number every year at NIH, although the average royalty to staffers there is only $9,000. In 2014 the NIH collected $147 million in royalties from all of its licenses, which includes medical tests and biological materials as well as drugs.

The advocacy group also requested the NIH allow outside researchers continue to look for new uses of the drug, make the research spending that Virotas does transparent to taxpayers, and allow the World Health Organization (WHO) to request a royalty-free license for NIH inventions. A WHO survey in April concluded that the newest hepatitis drugs were essentially "unaffordable" in 12 countries, such as Turkey and Egypt, where prices exceeded the average yearly income.

NIH staff vetted the firm's ability to shepherd a promising drug through the Food and Drug Administration's approval process, Rohrbaugh said. Fewer than 3 in 10 drugs that makes it as far as starting human volunteer testing runs this gantlet, where full blown trials can cost tens of millions of dollars apiece. The high cost of getting a drug approved means companies are unlikely to invest in licenses that come with price restrictions, he said.
Nevertheless, the US government retains "march in" rights on drugs to make them affordable, Annette Gaudino of the Treatment Action Group told BuzzFeed News by email. But those rights have only been used in wartime or after bioterrorism events. Refusal to intervene in the case of costly drugs, or to cut off unreasonable prices before they start with licenses, she said, raises questions about NIH's rationale for licensing drugs.

"Costs are real, but price is a choice," Gaudino said. "This gets right to the heart of what government is for: To intervene when necessary to preserve the common good, or to smooth the way for entrenched interests?"

But even if the NIH made "reasonable price" requirements a part of its drug licenses, it might not make a difference, said David Evans of Project Inform, an advocacy group for affordable HIV and hepatitis drugs.

"What we claim is the price of a drug, whether it's $84,000 or $300,000 is almost meaningless," he told BuzzFeed News. "Drug pricing in the US is so complicated," he said, because in reality there isn't really a free market for drugs, but a bewildering kaleidoscope of agreements between hospitals, insurers, clinics, and federal programs such as Medicare, all paying different discounts and rates for medicine.

Some very expensive drugs are sold at deep discount to clinics for low-income patients, Evans noted, and forcing a uniform price on them, might actually raise the price for the most vulnerable. "That makes prices a very difficult calculation for anyone to make, much less asking folks inside NIH to figure it out."

For that reason, Love suggested that NIH get out of the drug licensing business and that such deals should be handled by the Treasury Department or Medicare accountants more interested in the bottom line. "Other countries are paying less for these drugs we paid to invent," Love said. "There should be some limits."

--
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Ip-health@lists.keionline.org
http://lists.keionline.org/mailman/listinfo/ip-health_lists.keionline.org

From: Plude, Denise (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/CN=RECIPIENTS/CN=PARKSDE]
Sent: 4/1/2016 1:39:00 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=OD/cn=ROHRBAUM]
Subject: RE: WF 345473 - Response Creation due 4/1

Reminder this is due by noon today.

From: Carr, Sarah (NIH/OD) [E]
Sent: Friday, March 25, 2016 12:23 PM
To: Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>
Cc: Plude, Denise (NIH/OD) [E] <pludede@mail.nih.gov>
Subject: FW: WF 345473 - Response Creation due 4/1

Mark,

See instructions below.

Sarah

From: Plude, Denise (NIH/OD) [E]
Sent: Friday, March 25, 2016 12:19 PM
To: Carr, Sarah (NIH/OD) [E] <CarrS@OD.NIH.GOV>
Subject: WF 345473 - Response Creation due 4/1

Work Folder Information
Work Folder: WF 345473
Process: Response Creation
Program Analyst: Twyman, Leslie (NIH/OD) [E]
Due Date: April 01, 2016
WF Subject: Supports the Union for Affordable Cancer Treatment and Knowledge Ecology International's request that the NIH use the government's march-in rights in patents on the prostate cancer drug enzalutamide (marketed at Xtandi).
IC: od_osp
From: Ramachandran, Reshma
To: Collins, Francis
Remarks: Assigned to OSP to work with OER and OTT to prepare a Dir Sig response by noon on 4/1/16. Info copies to OER, OTT, NCI and OGC (DIR, DEPD, and DDSOP already received an info copy). Thank you, Leslie Twyman for Lisa Marshall (workfolder 345473).

From: Fennington, Kelly (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/CN=OD/CN=FENNINGTONKNEW]
Sent: 3/31/2016 1:06:23 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=OD/cn=ROHRBAUM]
Subject: RE: Carrie's next 1:1 with KH

Thanks Mark.

Kelly

From: Rohrbaugh, Mark (NIH/OD) [E]
Sent: Thursday, March 31, 2016 9:04 AM
To: Fennington, Kelly (NIH/OD) [E] <FenningK@OD.NIH.GOV>
Subject: RE: Carrie's next 1:1 with KH

Attached is the draft response to the march-in request for Xtandi that Ann Hammersla sent to KH on 3/22. The draft

b5

On March 28, 2016, Sen. Sanders, Rep. Doggett and 10 other Members of Congress issued a letter to NIH requesting that NIH hold a public hearing regarding the pending request to exercise its march-in rights for Xtandi (a prostate cancer drug developed by UCLA through grants from the NIH and the U.S. Army). HHS Secretary Burwell, NIH Director Collins, and DoD Secretary Ashton Carter received a request from Knowledge Ecology International and the Union for Affordable Cancer Treatment to exercise its march in authority in this case on January 14, 2016, based on the high retail price of this drug relative to the cost to governments in other Western countries. b5

b5

b5

From: Fennington, Kelly (NIH/OD) [E]
Sent: Thursday, March 31, 2016 8:47 AM
To: Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>
Subject: RE: Carrie's next 1:1 with KH

Hi Mark,

Can you give me a few bullets or details that I can add to this topic. Do you have the draft response?

Thanks,
Kelly

From: Rohrbaugh, Mark (NIH/OD) [E]
Sent: Wednesday, March 30, 2016 9:50 AM
To: Fennington, Kelly (NIH/OD) [E] <FenningK@OD.NIH.GOV>
Cc: Carr, Sarah (NIH/OD) [E] <CarrS@OD.NIH.GOV>; Jorgenson, Lyric (NIH/OD) [E] <jorgensonla@od.nih.gov>; Volkov, Marina (NIH/OD) [E] <mvolkov@od.nih.gov>; Paltoo, Dina (NIH/OD) [E] <paltood@od.nih.gov>; Bayha, Ryan (NIH/OD)

[E] <bayhar@od.nih.gov>
Subject: Re: Carrie's next 1:1 with KH

Draft response from HHS to Congress Is due to Exec sec on Friday, so it may still be in KH's queue on Tues

Sent from my iPhone

On Mar 29, 2016, at 2:22 PM, Fennington, Kelly (NIH/OD) [E] <FenningK@OD.NIH.GOV> wrote:

> Thanks Mark.
>
> Kelly
>
> ---
>
> **From:** Rohrbaugh, Mark (NIH/OD) [E]
> **Sent:** Tuesday, March 29, 2016 1:17 PM
> **To:** Fennington, Kelly (NIH/OD) [E] <FenningK@OD.NIH.GOV>
> **Cc:** Carr, Sarah (NIH/OD) [E] <CarrS@OD.NIH.GOV>; Jorgenson, Lyric (NIH/OD) [E] <jorgensonla@od.nih.gov>; Volkov, Marina (NIH/OD) [E] <mvolkov@od.nih.gov>; Paltoo, Dina (NIH/OD) [E] <paltood@od.nih.gov>; Bayha, Ryan (NIH/OD) [E] <bayhar@od.nih.gov>
> **Subject:** Re: Carrie's next 1:1 with KH
>
> plans for response to March-in petition and Congressional request for public "hearing"
>
> Sent from my iPhone
>
> On Mar 29, 2016, at 12:43 PM, Fennington, Kelly (NIH/OD) [E] <FenningK@OD.NIH.GOV> wrote:
>
> > Good Afternoon All,
> >
> > Carrie's next 1:1 with Kathy is scheduled for Tuesday, April 5 at 10:00 AM. Please send me any items you would like to add to the meeting agenda by COB, Thursday, March 31.
> >
> > Thanks,
> > Kelly
> >
> > Kelly T. Fennington
> > Chief of Staff
> > Office of Science Policy
> > Office of the Director
> >
> > Please follow us on Twitter: @CWolinetzNIH
> > Subscribe to "Under the Poliscope" NIH OSP's new blog!
> >
> > <image003.png>

From: Carr, Sarah (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/CN=OD/CN=CARRS]
Sent: 3/25/2016 4:22:53 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=OD/cn=ROHRBAUM]
CC: Plude, Denise (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=Recipients/cn=parksde]
Subject: FW: WF 345473 - Response Creation due 4/1
Attachments: email.pdf; incoming.pdf

Mark,

See instructions below.

Sarah

From: Plude, Denise (NIH/OD) [E]
Sent: Friday, March 25, 2016 12:19 PM
To: Carr, Sarah (NIH/OD) [E] <CarrS@OD.NIH.GOV>
Subject: WF 345473 - Response Creation due 4/1

Work Folder Information

Work Folder: WF 345473
Process: Response Creation
Program Analyst: Twyman, Leslie (NIH/OD) [E]
Due Date: April 01, 2016
WF Subject: Supports the Union for Affordable Cancer Treatment and Knowledge Ecology International's request that the NIH use the government's march-in rights in patents on the prostate cancer drug enzalutamide (marketed at Xtandi).
IC: od_osp
From: Ramachandran, Reshma
To: Collins, Francis
Remarks: Assigned to OSP to work with OER and OTT to prepare a Dir Sig response by noon on 4/1/16. Info copies to OER, OTT, NCI and OGC (DIR, DEPD, and DDSOP already received an info copy). Thank you, Leslie Twyman for Lisa Marshall (workfolder 345473).

Reshma Ramachandran

From:Reshma Ramachandran
Sent:21 Mar 2016 14:01:55 -0400
To:Collins, Francis (NIH/OD) [E]
Cc:Burwell, Sylvia M. (HHS/OS);Hammersla, Ann (NIH/OD) [E]
Subject:Letter from 11 NGOs calling for NIH to take action on high drug prices
Attachments:NGO-xtandi-support-letter-March-21-2016.pdf

Dear Director Collins:

Attached, please find a letter signed by eleven nongovernmental organizations in support of the request by Knowledge Ecology International and the Union for Affordable Cancer Treatment that the NIH use the government's rights in patents on the prostate cancer drug enzalutamide (marketed as Xtandi). We call upon you to hold an open and transparent public hearing to discuss the issues raised by that request and welcome any further discussion.

Sincerely,

Reshma Ramachandran
National Physicians Alliance

--

Reshma Ramachandran, MD MPP
Assistant Scientist (Research Faculty), Environmental Health Sciences
Johns Hopkins Bloomberg School of Public Health
ReAct-Action on Antibiotic Resistance Strategic Policy Program
National Physicians Alliance FDA Task Force Co-Chair
e: b6
m
t: https://twitter.com/reshmagar

Francis Collins, M.D., Ph.D.
Director National Institutes of Health
9000 Rockville Pike
Bethesda, MD 20892
via: francis.collins@nih.hhs.gov

March 21, 2016

Dear Director Collins,

We are writing in support of the request by the Union for Affordable Cancer Treatment (UACT) and Knowledge Ecology International (KEI) that the NIH use the government's rights in patents on the prostate cancer drug enzalutamide (marketed as Xtandi). The request highlighted the problems of access created through Japan-based Astellas Pharma's price of more than $350 per day in the United States, or $129,000 per year, for a federally-funded cancer drug invented on U.S. government grants. This price is exorbitant in its own right, but is particularly concerning in light of the fact that it is two to four times more than the company charges cancer patients in other high-income countries.

The first step is to hold a hearing on this request, and to allow the public to weigh in on this important dispute.

As the petition notes, the NIH has two options under the Bayh-Dole Act to address the concerns raised. It can use the royalty-free rights in the patents (under 35 U.S.C. § 202[1]), an option that requires the payment of no royalties to Astellas, no finding of abuse, and which is not subject to appeals. Or, it can use its "march-in rights" as described in 35 U.S.C. § 203, an option that requires a finding of abuse, payment of royalties, and allows Astellas special appeal rights.[2] We believe that the royalty-free option makes more sense, as it eliminates any question about the authority to act.

In either case, a transparent, public hearing to have a serious and thorough discussion of the important issues raised regarding this drug, its price, and access is important to patients and consumers, and may have a deterrent effect of its own right with regard to pricing, distinct from the outcome of the NIH's internal deliberations.

The undersigned groups represent, among others, taxpayers who gladly support the NIH budget because innovation is important. But the NIH must also appreciate that the public is concerned by the high prices of all drugs in the United States, in particular life-saving cancer drugs, and that some answers may lie in plain view. We note the recent letter from Rep. Doggett and fifty other members of Congress specifically calling on the NIH to issue guidelines on march-in rights and excessive prices.

---

[1] 35 U.S.C. § 202(c)(4) "With respect to any invention in which the contractor elects rights, the Federal agency shall have a nonexclusive, nontransferrable *[sic]*, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States any subject invention throughout the world."

[2] 35 U.S.C. § 201 defines "Practical Application" as requiring that the invention "is being utilized and that its benefits are ... available to the public **on reasonable terms**." (Emphasis added.)

The price of cancer drugs is critically important, and we urge the NIH to take this opportunity to act.

Sincerely Yours,

Alliance for Retired Americans
American Medical Students Association (AMSA)
Center for the Study of Responsive Law
Community Catalyst
Essential Information
National Physicians Alliance (NPA)
Public Citizen
RxRights
The Other 98%
Universities Allied for Essential Medicines (UAEM)
U.S. PIRG

cc: Sylvia Mathews Burwell, Secretary of Health and Human Services; Douglas R. Lowy, M.D., Acting Director, National Cancer Institute; Ann M. Hammersla, Director, NIH Division of Extramural Inventions and Technology Resources and Office of Policy for Extramural Research Administration (OPERA)

From: Hammersla, Ann (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/CN=RECIPIENTS/CN=HAMMERSLAA]
Sent: 1/3/2017 12:13:04 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=OD/cn=ROHRBAUM]
Subject: FW: If Taxpayers Invent A Drug, Should The Government Just Give It Away?

FYI

What if the taxpayer money invented a better treatment for hepatitis, and then just gave it away?

Officials at the National Institutes of Health said that's exactly how it's supposed to work, when queried over public records that show the federal research agency licensed out a potential new hepatitis drug while spurning calls to require the company to set "reasonable prices" for consumers.

"It would be unfortunate," an NIH official, Anna Amar, wrote in a 2015 email, if questioning of the deal by public interest groups, "bothers the company enough to reconsider the license."

In spite of the questions, the NIH completed the licensing deal with an unknown start-up called Virotas LLC in April of 2015. It was one of about 80 such cooperative research and development agreements (CRADA's) that the federal research agency signs every year. "All we are doing is asking some reasonable questions about giving away the rights to a promising drug," James Love of public interest group Knowledge Ecology International, told BuzzFeed News. "Why would you exclusively license the rights to a promising drug to an unknown firm with no track record?"

"We take it seriously, but it is not our mission to control drug prices," NIH technology transfer chief Mark Rohrbaugh told BuzzFeed News. Previous efforts to work price restrictions into such agreements scared away firms and ended in 1995, he said. . . . "The return to taxpayers is new drugs to the public," Rohrbaugh said.

From: Scott Cooper [b6]
Sent: Monday, January 02, 2017 10:37 PM
To: Cooper, Scott (NIH/OD) [E] <coopersa2@od.nih.gov>
Subject: If Taxpayers Invent A Drug, Should The Government Just Give It Away?

If Taxpayers Invent A Drug, Should The Government Just Give It Away?

Sent from the BuzzFeed app

From: Gadhia, Ami (NIH/NCATS) [E] [/O=NIH/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=GADHIAAD353]
Sent: 12/20/2016 2:47:33 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=OD/cn=ROHRBAUM]
Subject: RE: NYT: Harnessing the U.S. Taxpayer to Fight Cancer and Make Profits

Mark,

This article was an interesting read. Thanks for sharing it.

Best regards,

Ami Gadhia, J.D., LL.M., C.L.P.
Technology Transfer and Patenting Specialist
(301) 217-6098
Ami.gadhia@nih.gov
Office of Strategic Alliances
National Center for Advancing Translational Sciences (NCATS)
National Institutes of Health (NIH)

NIH NCATS: Improving Health Through Smarter Science
Connect with us!: https://ncats.nih.gov/connect

From: Rohrbaugh, Mark (NIH/OD) [E]
Sent: Tuesday, December 20, 2016 7:06 AM
To: NIH TDC Long <niaaatdcl-l@mail.nih.gov>; OD-OTT <OD-OTT@OD.NIH.GOV>
Subject: Fwd: NYT: Harnessing the U.S. Taxpayer to Fight Cancer and Make Profits

Sent from my iPhone

Begin forwarded message:

> **From:** "Myles, Renate (NIH/OD) [E]" <mylesr@od.nih.gov>
> **Date:** December 19, 2016 at 9:33:05 PM EST
> **To:** "Collins, Francis (NIH/OD) [E]" <collinsf@od.nih.gov>, NIH Director's Executive Committee <OD-SmallStaff@mail.nih.gov>
> **Cc:** "Jackson, Calvin (NIH/OD) [E]" <JACKSONC@od31tm1.od.nih.gov>, OCPLPressTeam <OCPLPressTeam@od.nih.gov>, "Rohrbaugh, Mark (NIH/OD) [E]" <RohrBauM@OD.NIH.GOV>, "Kassilke, Deborah (NIH/OD) [E]" <deborah.kassilke@nih.gov>
> **Subject: NYT: Harnessing the U.S. Taxpayer to Fight Cancer and Make Profits**
>
> # New York Times
>
> ## Health

Harnessing the U.S. Taxpayer to Fight Cancer and Make Profits

By MATT RICHTEL and ANDREW POLLACK DEC. 19, 2016

Dr. Steven Rosenberg, left, who has led the surgery branch at the National Cancer Institute for 42 years, and Dr. Arie Belldegrun, the founder of Kite Pharma. Credit Jesse Dittmar (left) and Emily Berl (right) for The New York Times

Enthusiasm for cancer immunotherapy is soaring, and so is Arie Belldegrun's fortune.

Dr. Belldegrun, a physician, co-founded Kite Pharma, a company that could be the first to market next year with a highly anticipated new immunotherapy treatment. But even without a product, Dr. Belldegrun has struck gold.

His stock in Kite is worth about $170 million. Investors have profited along with him, as the company's share price has soared to about $50 from an initial price of $17 in 2014.

The results reflect widespread excitement over immunotherapy, which harnesses the body's immune system to attack cancer and has rescued some patients from near-certain death. But they also speak volumes about the value of Kite's main scientific partner: the United States government.

Kite's treatment, a form of immunotherapy called CAR-T, was initially developed by a team of researchers at the National Cancer Institute, led by a longtime friend and mentor of Dr.

Belldegrun. Now Kite pays several million a year to the government to support continuing research dedicated to the company's efforts.

The relationship puts American taxpayers squarely in the middle of one of the hottest new drug markets. It also raises a question: Are taxpayers getting a good deal?

Defenders say that the partnership will likely bring a lifesaving treatment to patients, something the government cannot really do by itself, and that that is what matters most.

Critics say that taxpayers will end up paying twice for the same drug — once to support its development and a second time to buy it — while the company reaps the financial benefit.

"If this was not a government-funded cancer treatment — if it was for a new solar technology, for example — it would be scandalous to think that some private investors are reaping massive profits off a taxpayer-funded invention," said James Love, director of Knowledge Ecology International, an advocacy group concerned with access to medicines.

Photo

Dr. Rosenberg and Dr. Belldegrun in the mid-1980s. Dr. Belldegrun became a research fellow for Dr. Rosenberg at the cancer institute in 1985. Credit Kite Pharma

The debate goes squarely to one of the nation's most vexing challenges: rising health care and drug prices. Kite is one of a growing number of drug and biotech companies relying on federal laboratories. Analysts expect the company to charge at least $200,000 for the new treatment, which is intended as a one-time therapy for patients.

While the law allows the government to demand drug-price concessions from its private-sector partners, the government has declined to do so with Kite and generally disdains the practice.

Insisting on lower prices, federal researchers say, would drive away innovative partners that speed the drug-development process and benefit patients. But with the government doing so much pivotal research, others say that the private sector cannot afford to walk away.

“The market is so reliant on the knowledge and know-how that comes out of the government and academic labs,” said Dr. Aaron Kesselheim, director of the Program on Regulation, Therapeutics and Law at Brigham & Women’s Hospital in Boston.

Price curbs, he said, “would not suddenly lead to a total abandonment of this pipeline. It couldn’t possibly.”

Drug makers would be especially unlikely to turn away from immunotherapy, where the promising science has set off a “gold rush mentality,” according to Mark Edwards of Bioscience Advisors, a company which tracks pharmaceutical licensing deals.

The National Institutes of Health, the parent agency of the National Cancer Institute, currently has about 400 cooperative research agreements with companies, and licenses hundreds of patented inventions for private-sector development.

Kite executives and national health officials characterize their partnership as a model arrangement in a system established by Congress three decades ago. The system has given birth to the cancer drug Taxol, the AIDS drug Prezista, two cervical cancer vaccines and a widely used test for H.I.V. infection, among other innovations.

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Photo

Dr. Rosenberg in his lab at the cancer institute in Bethesda, Md. Partnerships between government labs and drug companies are “absolutely essential or many discoveries will not see the light of day,” he said. Credit Jesse Dittmar for The New York Times

Kite’s first drug, called KTE-C19, could help thousands of patients each year in the United States with certain blood cancers. If it succeeds, it could generate sales of $1 billion to $2 billion annually, according to Wall Street analysts, making it among the most lucrative drugs to come from government research.

But the government’s share of any Kite success would be modest, much lower than some academic research groups have wrangled in immunotherapy deals worth hundreds of millions of dollars. Federal officials counter that the reward to the taxpayer is not money but the drug itself.

“This is exactly the way things should work,” said Dr. Steven Rosenberg, who has led the surgery branch at the National Cancer Institute for 42 years and led development of Kite’s drug. Such partnerships, he said, are “absolutely essential or many discoveries will not see the light of day.”

Moreover, government officials say, companies in such deals must take significant financial risks and expenditures on their own, without any guarantee that the drug will be approved.

Kite says it has spent more than $200 million on research and development, including running larger clinical trials than those conducted by the cancer institute, and recently spent about $30 million to build a factory that will be able to make treatments for up to 5,000 patients a year.

Setting the price of the drug, Dr. Rosenberg said, “is for the marketplace.”

A Public-Private Partnership

Like many business deals, this one began with a personal relationship — in this case between Dr. Rosenberg and Dr. Belldegrun.

After finishing medical school in his native Israel, performing surgery in helicopters for the Israeli armed forces, and completing residency at Brigham & Women’s Hospital, Dr. Belldegrun became a research fellow for Dr. Rosenberg at the N.C.I. It was 1985, and Dr. Belldegrun was put to work on a new project of Dr. Rosenberg’s — extracting tumor-fighting immune cells from cancer patients, multiplying them in the laboratory, and putting them back in.

“He was one of the more outstanding fellows to come through,” said Dr. Rosenberg, 76, who is widely considered a cancer research luminary.

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Photo

Dr. Belldegrun, center, at the Nasdaq stock exchange, where Kite Pharma is listed. The company was founded in 2009 and went public in 2014. Credit Nasdaq, 2016

When the fellowship ended in 1988, Dr. Belldegrun became a prominent surgeon at the University of California, Los Angeles, but the two men stayed in touch. Eventually, Dr. Belldegrun, 67, got the entrepreneurial bug. He co-founded a biotech company, Agensys, which was acquired by a bigger company for more than $500 million. He was also involved with Cougar Biotechnology, which developed the prostate cancer drug Zytiga and was acquired by Johnson & Johnson for $1 billion in May 2009. A month later, Dr. Belldegrun formed Kite with a group of colleagues and investors to pursue cancer immunotherapy.

That same month, a Florida marine contractor named Eric Karlson, whose non-Hodgkin's lymphoma was advancing despite four prior treatments, became the first patient treated by Dr. Rosenberg with what would eventually become KTE-C19. The treatment entailed removing some of Mr. Karlson's immune system T cells from his blood, genetically engineering them to recognize and fight his cancer, multiplying the T cells to huge numbers in the laboratory and transferring them back into his body. After two such treatments, Mr. Karlson remains alive and cancer-free eight years later.

Kite initially thought it would pursue an approach to immunotherapy known as cancer vaccines, but in 2010, Dr. Belldegrun visited Dr. Rosenberg and was shown the X-rays of Mr. Karlson and of a second patient.

Dr. Belldegrun was bowled over. "I had no doubt that this is going to be a drug and, more than that, it will become a platform for multiple products," he recalled. "We never looked back."

Over the next two years, the National Cancer Institute worked out a deal with Kite that was signed in 2012. It was the first of eight contracts between the government and the company that generally take two forms.

In one type of contract, Kite licenses patented inventions and agrees to pay the government royalties, roughly 5 percent of sales of any commercial product arising from a particular patent. However, there is no such license specifically for KTE-C19 because the underlying treatment was not patented by the N.C.I., so royalties will be minimal.

Officials say the agency did not apply for a patent because the treatment was similar to what others had been developing. Also, at the time the treatment was first created, in 2007, immunotherapy was considered to have dim commercial prospects.

"Back then, we didn't even think about commercial aspects," said Dr. James N. Kochenderfer, a scientist at the agency who designed the treatment when working in Dr. Rosenberg's group.

Under the second type of contract, known as a cooperative research and development agreement, Kite provides money to the N.C.I. to support research. Kite is now paying $3 million a year to Dr. Rosenberg's lab and has provided $7.5 million to it in total since 2012. Based on its regulatory filings, Kite is paying $7.8 million a year for research agreements and licenses in total, with at least $4 million of that going to the cancer institute and the rest to academic or corporate partners.

The taxpayer has invested, too. Dr. Rosenberg estimated that the government has spent roughly $10 million over the years on what has become KTE-C19. He said Kite's $3 million a year is about equal to the taxpayer funding in that area and has helped speed research.

These days, researchers from Kite and the cancer institute, typically including Dr. Rosenberg and Dr. Belldegrun, confer by conference call every other Thursday for 90 minutes. Kite employees have spent long periods at the N.C.I., learning how to manufacture the therapy and how to treat patients in advance with chemotherapy.

"We shouldn't underestimate the value and the importance of N.I.H., not only to Kite but to the whole field of engineered T-cell therapy," Dr. Belldegrun said. When Kite signed its first deal with the cancer agency, he said, it "tapped into six years of monumental work that they had done."

Some immunotherapy competitors marvel at the company's coup in tapping into the agency's expertise. "They got 20 years of research all together in one scoop," said Dr. Carlos Paya, chief executive of Immune Design, which is pursuing a different approach.

But government officials say few, if any, other companies were interested in the technology at the time Dr. Belldegrun came calling. Dr. Rosenberg said that before Kite, a few companies, including Johnson & Johnson, had looked at an earlier version of his technology but were wary because treatment involved processing each patient's cells.

Government-developed technology available to be licensed to companies is posted on the website of the National Institutes of Health. And when the agency intends to grant a license to a particular company, it publishes that in the Federal Register, inviting public comment and possible competing offers. Both steps were taken in the case of Kite, officials said.

Kite did not get everything the cancer institute has developed in the field. Some other companies, including Opus Bio and Bluebird Bio, got rights to some products, in part because the companies had special expertise that the agency's researchers desired. But Kite seems to have gotten the balance of them and N.C.I. technology accounts for the majority of its pipeline of possible products, though the company is diversifying.

Photo

A slide that Kite Pharma used in presentations to potential investors pointed out the company's relationship with Dr. Rosenberg.

Dr. Rosenberg professes no interest in the business side of the Kite relationship. He does not own stock in any company, even Kite, though he could get up to $150,000 a year in patent royalties if some of Kite's efforts pay off.

Dr. Belldegrun, in contrast to his mentor, has commercial flair. He is known for his sharp business suits, lives in the Bel-Air neighborhood of Los Angeles, and seems as comfortable on Wall Street or in high society as in the operating room.

Kite's relationship with the N.C.I. is an important part of its appeal to investors. In some presentations, Dr. Belldegrun has shown a photograph of himself with Dr. Rosenberg in their younger days. And he persuaded Dr. Rosenberg to speak at Kite's first big meeting for investors in June 2015, the only time he has ever spoken to Wall Street.

In emails obtained through a Freedom of Information Act request by Knowledge Ecology International, Dr. Belldegrun praised Dr. Rosenberg's talk and sent him copies of investment reports from the conference written by Wall Street analysts.

"Thank you for making the effort to come to NY," Dr. Belldegrun wrote. "I heard only raving reviews about your presence and presentation."

A 'Reasonable' Question

The reliance of private companies on government-funded research goes well beyond obvious cases like Kite. In many instances, companies work with universities or medical centers that, in turn, have been funded from the $32 billion annual budget of the National Institutes of Health.

Kite's two main competitors, Novartis and Juno Therapeutics, for instance, derived similar immunotherapy treatments largely from academic institutions, developed at least in part with government funding. Novartis has a relationship with the University of Pennsylvania, and Juno with the Memorial Sloan Kettering Cancer Center, the Fred Hutchinson Cancer Research Center and Seattle Children's Hospital.

"For the most important drugs you'll see some public-sector involvement," said Bhaven Sampat, an associate professor of health policy and management at Columbia University. He was one author of a study that found that 9 percent of all drugs approved between 1988 and 2005 were based directly on a patent held by the public sector. But 47.8 percent of the drugs relied at least indirectly on some federally funded research.

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Photo

Eric Karlson at his home on Marco Island, Fla., this month. Mr. Karlson's non-Hodgkin's lymphoma was successfully treated by Dr. Rosenberg with what would eventually become KTE-C19. Credit Scott McIntyre for The New York Times

The figures were higher for more medically important drugs: 17.4 percent had a direct public-sector patent, while 64.5 percent had at least an indirect public-sector influence.

These figures are up sharply from before the 1980s. Such partnerships and licensing deals were encouraged by the 1980 Bayh-Dole and Stevenson-Wydler Acts, and the 1986 Federal Technology Transfer Act. The laws are credited with jump-starting the biotechnology industry.

But from the beginning, some people questioned whether taxpayers were getting a bad deal.

Perhaps the best-known drug developed from a cooperative research and development agreement — the cancer drug Taxol — was the subject of several congressional hearings in the early 1990s that investigated whether the drug's maker, Bristol-Myers Squibb, charged too much and whether the government recouped enough of its investment. In the end, the pricing was left unchanged.

The N.I.H. argues that if it imposes pricing restrictions, it won't get partners. In fact, in 1995, it struck from its negotiating tactics a goal that prices be "reasonable."

"Companies will not take technologies from us if we say the government will decide in the future what the price will be," said Mark Rohrbaugh, who ran the technology transfer office at the institutes from 2001 to 2013 and is now an adviser to the agency. After the "reasonable price" clause was struck, he said, there was a threefold increase in partnership deals.

The N.I.H. can collect royalties from successful products to help offset the costs of the research, but so far these royalties have been small, amounting to an estimated $135 million in the last fiscal year from 870 licenses, with the bulk of the money coming from a small number of drugs.

"We're not preoccupied with financial value," Dr. Rohrbaugh said. "Our mission is treatment of people and improving public health."

In that regard, the government's bet on a small company like Kite, which might have seemed risky, appears to be paying off so far. Dr. Belldegrun has largely delivered on promises to raise money, assemble an experienced staff, build the factory, conduct clinical trials and begin to apply for regulatory approval. Once considered the underdog to Novartis and Juno, Kite might be the first reach the market.

Photo

Scans of Mr. Karlson’s body before and after his treatment. In the cross-sections on the left, the arrows point to signs of lymphoma in areas such as his armpits, chest, spleen and pelvis. Credit National Cancer Institute

Academic centers and companies often drive harder bargains in licensing technology. In some cases, academic centers own a stake in a company they license technology to, allowing them to reap a financial windfall if the company does well. Both the Hutchinson cancer center and Sloan Kettering have owned stock in Juno and are entitled to substantial payments — up to $350 million and $150 million — if Juno’s stock reaches certain levels.

The N.I.H. does not take equity positions in companies to avoid an appearance of a conflict of interest. So to critics of the government deals, drug prices are crucial to understanding taxpayer value. After all, they ask, is a drug truly widely available — which is what the government says is its measure of success — if it costs too much for some people?

Rachel Sachs, an associate law professor at Washington University in St. Louis and expert in innovation policy, said the government had every right to seek price concessions. She noted that the government, through Medicare and Medicaid, was effectively buying its inventions back from itself. “The public is paying for the research and to the extent that many people, if not most, will pay through public insurance, we’re paying again,” she said.

Hillary Clinton, in her campaign for president, promised to set new rules for federal support of research so that Americans “get the value they deserve” for the money taxpayers spend in supporting research. It is not clear how President-elect Donald J. Trump will approach these issues; he has said he favors reducing health care costs, but Republicans, who control Congress, too, have opposed government involvement in price setting.

One mechanism to control pricing already exists. It is called march-in rights, and it lets the N.I.H. take back control of a patent on an invention made with federal funding if the drug is not being made available to the public on reasonable terms. The tool has gone unused.

Earlier this year, Knowledge Ecology International and another advocacy group, the Union for Affordable Cancer Treatment, petitioned the agency to exercise march-in rights on Xtandi, a prostate cancer drug that was developed by federally funded researchers at U.C.L.A. It said the price in the United States of about $129,000 a year, two to four times that in other developed countries, meant the drug was not reasonably available. The effort was supported by other public interest groups and some Democratic members of Congress.

U.C.L.A. made more than $500 million by selling its royalty rights to the drug. But the N.I.H. declined to exercise its march-in rights on Xtandi, arguing that it was not qualified to judge whether a drug's price is reasonable and that a high price does not mean a drug is not being made available to the public.

"N.I.H. has made it clear that its job is not to decide prices of drugs, period," Dr. Rohrbaugh said

Kite says it has not decided what to charge for KTE-C19, but Dr. Belldegrun hinted that Kite's therapy might be relatively expensive because ideally it would be a single treatment that would cure the patient, not a drug that would have to be taken continuously. He added that Kite would take steps to make sure that everyone who needed the drug could get it.

Meantime, the relationship between Kite and the National Cancer Institute is expanding to develop treatments for other cancers, including one technique Dr. Rosenberg thinks could be used to attack solid tumors like colon, breast and lung cancer.

"The potential for broad applicability is huge," he said.

That could mean many lives saved and maybe more billion-dollar drugs for Kite and its investors, with the American taxpayer right in the middle of the deal.

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From: Burke, Andy (NIH/NCI) [E] [/O=NIH/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BURKEAR]
Sent: 12/20/2016 2:24:41 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=OD/cn=ROHRBAUM]
Subject: RE: NYT: Harnessing the U.S. Taxpayer to Fight Cancer and Make Profits

Hi Mark,

I read this when it came out yesterday afternoon. Not the most flattering take on the situation…

Andy

From: Rohrbaugh, Mark (NIH/OD) [E]
Sent: Tuesday, December 20, 2016 7:06 AM
To: NIH TDC Long <niaaatdcl-l@mail.nih.gov>; OD-OTT <OD-OTT@OD.NIH.GOV>
Subject: Fwd: NYT: Harnessing the U.S. Taxpayer to Fight Cancer and Make Profits

Sent from my iPhone

Begin forwarded message:

> **From:** "Myles, Renate (NIH/OD) [E]" <mylesr@od.nih.gov>
> **Date:** December 19, 2016 at 9:33:05 PM EST
> **To:** "Collins, Francis (NIH/OD) [E]" <collinsf@od.nih.gov>, NIH Director's Executive Committee <OD-SmallStaff@mail.nih.gov>
> **Cc:** "Jackson, Calvin (NIH/OD) [E]" <JACKSONC@od31tm1.od.nih.gov>, OCPLPressTeam <OCPLPressTeam@od.nih.gov>, "Rohrbaugh, Mark (NIH/OD) [E]" <RohrBauM@OD.NIH.GOV>, "Kassilke, Deborah (NIH/OD) [E]" <deborah.kassilke@nih.gov>
> **Subject: NYT: Harnessing the U.S. Taxpayer to Fight Cancer and Make Profits**
>
> # New York Times
>
> ## Health
>
> # Harnessing the U.S. Taxpayer to Fight Cancer and Make Profits
>
> By MATT RICHTEL and ANDREW POLLACK DEC. 19, 2016

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Dr. Steven Rosenberg, left, who has led the surgery branch at the National Cancer Institute for 42 years, and Dr. Arie Belldegrun, the founder of Kite Pharma. Credit Jesse Dittmar (left) and Emily Berl (right) for The New York Times

Enthusiasm for cancer immunotherapy is soaring, and so is Arie Belldegrun's fortune.

Dr. Belldegrun, a physician, co-founded Kite Pharma, a company that could be the first to market next year with a highly anticipated new immunotherapy treatment. But even without a product, Dr. Belldegrun has struck gold.

His stock in Kite is worth about $170 million. Investors have profited along with him, as the company's share price has soared to about $50 from an initial price of $17 in 2014.

The results reflect widespread excitement over immunotherapy, which harnesses the body's immune system to attack cancer and has rescued some patients from near-certain death. But they also speak volumes about the value of Kite's main scientific partner: the United States government.

Kite's treatment, a form of immunotherapy called CAR-T, was initially developed by a team of researchers at the National Cancer Institute, led by a longtime friend and mentor of Dr. Belldegrun. Now Kite pays several million a year to the government to support continuing research dedicated to the company's efforts.

The relationship puts American taxpayers squarely in the middle of one of the hottest new drug markets. It also raises a question: Are taxpayers getting a good deal?

Defenders say that the partnership will likely bring a lifesaving treatment to patients, something the government cannot really do by itself, and that that is what matters most.

Critics say that taxpayers will end up paying twice for the same drug — once to support its development and a second time to buy it — while the company reaps the financial benefit.

"If this was not a government-funded cancer treatment — if it was for a new solar technology, for example — it would be scandalous to think that some private investors are reaping massive profits off a taxpayer-funded invention," said James Love, director of Knowledge Ecology International, an advocacy group concerned with access to medicines.

Photo

Dr. Rosenberg and Dr. Belldegrun in the mid-1980s. Dr. Belldegrun became a research fellow for Dr. Rosenberg at the cancer institute in 1985. Credit Kite Pharma

The debate goes squarely to one of the nation's most vexing challenges: rising health care and drug prices. Kite is one of a growing number of drug and biotech companies relying on federal laboratories. Analysts expect the company to charge at least $200,000 for the new treatment, which is intended as a one-time therapy for patients.

While the law allows the government to demand drug-price concessions from its private-sector partners, the government has declined to do so with Kite and generally disdains the practice.

Insisting on lower prices, federal researchers say, would drive away innovative partners that speed the drug-development process and benefit patients. But with the government doing so much pivotal research, others say that the private sector cannot afford to walk away.

"The market is so reliant on the knowledge and know-how that comes out of the government and academic labs," said Dr. Aaron Kesselheim, director of the Program on Regulation, Therapeutics and Law at Brigham & Women's Hospital in Boston.

Price curbs, he said, “would not suddenly lead to a total abandonment of this pipeline. It couldn’t possibly.”

Drug makers would be especially unlikely to turn away from immunotherapy, where the promising science has set off a “gold rush mentality,” according to Mark Edwards of Bioscience Advisors, a company which tracks pharmaceutical licensing deals.

The National Institutes of Health, the parent agency of the National Cancer Institute, currently has about 400 cooperative research agreements with companies, and licenses hundreds of patented inventions for private-sector development.

Kite executives and national health officials characterize their partnership as a model arrangement in a system established by Congress three decades ago. The system has given birth to the cancer drug Taxol, the AIDS drug Prezista, two cervical cancer vaccines and a widely used test for H.I.V. infection, among other innovations.

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Photo

Dr. Rosenberg in his lab at the cancer institute in Bethesda, Md. Partnerships between government labs and drug companies are “absolutely essential or many discoveries will not see the light of day,” he said. Credit Jesse Dittmar for The New York Times

Kite’s first drug, called KTE-C19, could help thousands of patients each year in the United States with certain blood cancers. If it succeeds, it could generate sales of $1 billion to $2 billion annually, according to Wall Street analysts, making it among the most lucrative drugs to come from government research.

But the government's share of any Kite success would be modest, much lower than some academic research groups have wrangled in immunotherapy deals worth hundreds of millions of dollars. Federal officials counter that the reward to the taxpayer is not money but the drug itself.

"This is exactly the way things should work," said Dr. Steven Rosenberg, who has led the surgery branch at the National Cancer Institute for 42 years and led development of Kite's drug. Such partnerships, he said, are "absolutely essential or many discoveries will not see the light of day."

Moreover, government officials say, companies in such deals must take significant financial risks and expenditures on their own, without any guarantee that the drug will be approved.

Kite says it has spent more than $200 million on research and development, including running larger clinical trials than those conducted by the cancer institute, and recently spent about $30 million to build a factory that will be able to make treatments for up to 5,000 patients a year.

Setting the price of the drug, Dr. Rosenberg said, "is for the marketplace."

A Public-Private Partnership

Like many business deals, this one began with a personal relationship — in this case between Dr. Rosenberg and Dr. Belldegrun.

After finishing medical school in his native Israel, performing surgery in helicopters for the Israeli armed forces, and completing residency at Brigham & Women's Hospital, Dr. Belldegrun became a research fellow for Dr. Rosenberg at the N.C.I. It was 1985, and Dr. Belldegrun was put to work on a new project of Dr. Rosenberg's — extracting tumor-fighting immune cells from cancer patients, multiplying them in the laboratory, and putting them back in.

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Photo

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Dr. Belldegrun, center, at the Nasdaq stock exchange, where Kite Pharma is listed. The company was founded in 2009 and went public in 2014. Credit Nasdaq, 2016

When the fellowship ended in 1988, Dr. Belldegrun became a prominent surgeon at the University of California, Los Angeles, but the two men stayed in touch. Eventually, Dr. Belldegrun, 67, got the entrepreneurial bug. He co-founded a biotech company, Agensys, which was acquired by a bigger company for more than $500 million. He was also involved with Cougar Biotechnology, which developed the prostate cancer drug Zytiga and was acquired by Johnson & Johnson for $1 billion in May 2009. A month later, Dr. Belldegrun formed Kite with a group of colleagues and investors to pursue cancer immunotherapy.

That same month, a Florida marine contractor named Eric Karlson, whose non-Hodgkin's lymphoma was advancing despite four prior treatments, became the first patient treated by Dr. Rosenberg with what would eventually become KTE-C19. The treatment entailed removing some of Mr. Karlson's immune system T cells from his blood, genetically engineering them to recognize and fight his cancer, multiplying the T cells to huge numbers in the laboratory and transferring them back into his body. After two such treatments, Mr. Karlson remains alive and cancer-free eight years later.

Kite initially thought it would pursue an approach to immunotherapy known as cancer vaccines, but in 2010, Dr. Belldegrun visited Dr. Rosenberg and was shown the X-rays of Mr. Karlson and of a second patient.

Dr. Belldegrun was bowled over. "I had no doubt that this is going to be a drug and, more than that, it will become a platform for multiple products," he recalled. "We never looked back."

Over the next two years, the National Cancer Institute worked out a deal with Kite that was signed in 2012. It was the first of eight contracts between the government and the company that generally take two forms.

In one type of contract, Kite licenses patented inventions and agrees to pay the government royalties, roughly 5 percent of sales of any commercial product arising from a particular patent. However, there is no such license specifically for KTE-C19 because the underlying treatment was not patented by the N.C.I., so royalties will be minimal.

Officials say the agency did not apply for a patent because the treatment was similar to what others had been developing. Also, at the time the treatment was first created, in 2007, immunotherapy was considered to have dim commercial prospects.

"Back then, we didn't even think about commercial aspects," said Dr. James N. Kochenderfer, a scientist at the agency who designed the treatment when working in Dr. Rosenberg's group.

Under the second type of contract, known as a cooperative research and development agreement, Kite provides money to the N.C.I. to support research. Kite is now paying $3 million a year to Dr. Rosenberg's lab and has provided $7.5 million to it in total since 2012. Based on its regulatory filings, Kite is paying $7.8 million a year for research agreements and licenses in total, with at least $4 million of that going to the cancer institute and the rest to academic or corporate partners.

The taxpayer has invested, too. Dr. Rosenberg estimated that the government has spent roughly $10 million over the years on what has become KTE-C19. He said Kite's $3 million a year is about equal to the taxpayer funding in that area and has helped speed research.

These days, researchers from Kite and the cancer institute, typically including Dr. Rosenberg and Dr. Belldegrun, confer by conference call every other Thursday for 90 minutes. Kite employees have spent long periods at the N.C.I., learning how to manufacture the therapy and how to treat patients in advance with chemotherapy.

"We shouldn't underestimate the value and the importance of N.I.H., not only to Kite but to the whole field of engineered T-cell therapy," Dr. Belldegrun said. When Kite signed its first deal with the cancer agency, he said, it "tapped into six years of monumental work that they had done."

Some immunotherapy competitors marvel at the company's coup in tapping into the agency's expertise. "They got 20 years of research all together in one scoop," said Dr. Carlos Paya, chief executive of Immune Design, which is pursuing a different approach.

But government officials say few, if any, other companies were interested in the technology at the time Dr. Belldegrun came calling. Dr. Rosenberg said that before Kite, a few companies, including Johnson & Johnson, had looked at an earlier version of his technology but were wary because treatment involved processing each patient's cells.

Government-developed technology available to be licensed to companies is posted on the website of the National Institutes of Health. And when the agency intends to grant a license to a particular company, it publishes that in the Federal Register, inviting public comment and possible competing offers. Both steps were taken in the case of Kite, officials said.

Kite did not get everything the cancer institute has developed in the field. Some other companies, including Opus Bio and Bluebird Bio, got rights to some products, in part because the companies had special expertise that the agency's researchers desired. But Kite seems to have gotten the balance of them and N.C.I. technology accounts for the majority of its pipeline of possible products, though the company is diversifying.

Photo

A slide that Kite Pharma used in presentations to potential investors pointed out the company's relationship with Dr. Rosenberg.

Dr. Rosenberg professes no interest in the business side of the Kite relationship. He does not own stock in any company, even Kite, though he could get up to $150,000 a year in patent royalties if some of Kite's efforts pay off.

Dr. Belldegrun, in contrast to his mentor, has commercial flair. He is known for his sharp business suits, lives in the Bel-Air neighborhood of Los Angeles, and seems as comfortable on Wall Street or in high society as in the operating room.

Kite's relationship with the N.C.I. is an important part of its appeal to investors. In some presentations, Dr. Belldegrun has shown a photograph of himself with Dr. Rosenberg in their younger days. And he persuaded Dr. Rosenberg to speak at Kite's first big meeting for investors in June 2015, the only time he has ever spoken to Wall Street.

In emails obtained through a Freedom of Information Act request by Knowledge Ecology International, Dr. Belldegrun praised Dr. Rosenberg's talk and sent him copies of investment reports from the conference written by Wall Street analysts.

"Thank you for making the effort to come to NY," Dr. Belldegrun wrote. "I heard only raving reviews about your presence and presentation."

A 'Reasonable' Question

The reliance of private companies on government-funded research goes well beyond obvious cases like Kite. In many instances, companies work with universities or medical centers that, in turn, have been funded from the $32 billion annual budget of the National Institutes of Health.

Kite's two main competitors, Novartis and Juno Therapeutics, for instance, derived similar immunotherapy treatments largely from academic institutions, developed at least in part with government funding. Novartis has a relationship with the University of Pennsylvania, and Juno with the Memorial Sloan Kettering Cancer Center, the Fred Hutchinson Cancer Research Center and Seattle Children's Hospital.

"For the most important drugs you'll see some public-sector involvement," said Bhaven Sampat, an associate professor of health policy and management at Columbia University. He was one author of a study that found that 9 percent of all drugs approved between 1988 and 2005 were based directly on a patent held by the public sector. But 47.8 percent of the drugs relied at least indirectly on some federally funded research.

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Photo

Eric Karlson at his home on Marco Island, Fla., this month. Mr. Karlson's non-Hodgkin's lymphoma was successfully treated by Dr. Rosenberg with what would eventually become KTE-C19. Credit Scott McIntyre for The New York Times

The figures were higher for more medically important drugs: 17.4 percent had a direct public-sector patent, while 64.5 percent had at least an indirect public-sector influence.

These figures are up sharply from before the 1980s. Such partnerships and licensing deals were encouraged by the 1980 Bayh-Dole and Stevenson-Wydler Acts, and the 1986 Federal Technology Transfer Act. The laws are credited with jump-starting the biotechnology industry.

But from the beginning, some people questioned whether taxpayers were getting a bad deal.

Perhaps the best-known drug developed from a cooperative research and development agreement — the cancer drug Taxol — was the subject of several congressional hearings in the early 1990s that investigated whether the drug's maker, Bristol-Myers Squibb, charged too much and whether the government recouped enough of its investment. In the end, the pricing was left unchanged.

The N.I.H. argues that if it imposes pricing restrictions, it won't get partners. In fact, in 1995, it struck from its negotiating tactics a goal that prices be "reasonable."

"Companies will not take technologies from us if we say the government will decide in the future what the price will be," said Mark Rohrbaugh, who ran the technology transfer office at the institutes from 2001 to 2013 and is now an adviser to the agency. After the "reasonable price" clause was struck, he said, there was a threefold increase in partnership deals.

The N.I.H. can collect royalties from successful products to help offset the costs of the research, but so far these royalties have been small, amounting to an estimated $135 million in the last fiscal year from 870 licenses, with the bulk of the money coming from a small number of drugs.

"We're not preoccupied with financial value," Dr. Rohrbaugh said. "Our mission is treatment of people and improving public health."

In that regard, the government's bet on a small company like Kite, which might have seemed risky, appears to be paying off so far. Dr. Belldegrun has largely delivered on promises to raise money, assemble an experienced staff, build the factory, conduct clinical trials and begin to apply for regulatory approval. Once considered the underdog to Novartis and Juno, Kite might be the first reach the market.

Photo

Scans of Mr. Karlson's body before and after his treatment. In the cross-sections on the left, the arrows point to signs of lymphoma in areas such as his armpits, chest, spleen and pelvis. Credit National Cancer Institute

Academic centers and companies often drive harder bargains in licensing technology. In some cases, academic centers own a stake in a company they license technology to, allowing them to reap a financial windfall if the company does well. Both the Hutchinson cancer center and Sloan Kettering have owned stock in Juno and are entitled to substantial payments — up to $350 million and $150 million — if Juno's stock reaches certain levels.

The N.I.H. does not take equity positions in companies to avoid an appearance of a conflict of interest. So to critics of the government deals, drug prices are crucial to understanding taxpayer value. After all, they ask, is a drug truly widely available — which is what the government says is its measure of success — if it costs too much for some people?

Rachel Sachs, an associate law professor at Washington University in St. Louis and expert in innovation policy, said the government had every right to seek price concessions. She noted that the government, through Medicare and Medicaid, was effectively buying its inventions back from itself. "The public is paying for the research and to the extent that many people, if not most, will pay through public insurance, we're paying again," she said.

Hillary Clinton, in her campaign for president, promised to set new rules for federal support of research so that Americans "get the value they deserve" for the money taxpayers spend in supporting research. It is not clear how President-elect Donald J. Trump will approach these issues; he has said he favors reducing health care costs, but Republicans, who control Congress, too, have opposed government involvement in price setting.

One mechanism to control pricing already exists. It is called march-in rights, and it lets the N.I.H. take back control of a patent on an invention made with federal funding if the drug is not being made available to the public on reasonable terms. The tool has gone unused.

Earlier this year, Knowledge Ecology International and another advocacy group, the Union for Affordable Cancer Treatment, petitioned the agency to exercise march-in rights on Xtandi, a prostate cancer drug that was developed by federally funded researchers at U.C.L.A. It said the price in the United States of about $129,000 a year, two to four times that in other developed countries, meant the drug was not reasonably available. The effort was supported by other public interest groups and some Democratic members of Congress.

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From: Chatterjee, Sabarni (NIH/NCI) [E] [/O=NIH/OU=NIHEXCHANGE/CN=RECIPIENTS/CN=CHATTERJEESA]
Sent: 12/20/2016 1:46:27 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=OD/cn=ROHRBAUM]
Subject: RE: NYT: Harnessing the U.S. Taxpayer to Fight Cancer and Make Profits

Hello Mark,

I saw the article yesterday. They did not mention our articles, rather used Sampat's. Hope things are going well at your end.

Happy Holidays!

Regards,
Sabarni

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Sent: Tuesday, December 20, 2016 7:06 AM
To: NIH TDC Long <niaaatdcl-l@mail.nih.gov>; OD-OTT <OD-OTT@OD.NIH.GOV>
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Sent from my iPhone

Begin forwarded message:

> **From:** "Myles, Renate (NIH/OD) [E]" <mylesr@od.nih.gov>
> **Date:** December 19, 2016 at 9:33:05 PM EST
> **To:** "Collins, Francis (NIH/OD) [E]" <collinsf@od.nih.gov>, NIH Director's Executive Committee <OD-SmallStaff@mail.nih.gov>
> **Cc:** "Jackson, Calvin (NIH/OD) [E]" <JACKSONC@od31tm1.od.nih.gov>, OCPLPressTeam <OCPLPressTeam@od.nih.gov>, "Rohrbaugh, Mark (NIH/OD) [E]" <RohrBauM@OD.NIH.GOV>, "Kassilke, Deborah (NIH/OD) [E]" <deborah.kassilke@nih.gov>
> **Subject: NYT: Harnessing the U.S. Taxpayer to Fight Cancer and Make Profits**

New York Times

Health

Harnessing the U.S. Taxpayer to Fight Cancer and Make Profits

By MATT RICHTEL and ANDREW POLLACK DEC. 19, 2016

Dr. Steven Rosenberg, left, who has led the surgery branch at the National Cancer Institute for 42 years, and Dr. Arie Belldegrun, the founder of Kite Pharma. Credit Jesse Dittmar (left) and Emily Berl (right) for The New York Times

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Dr. Rosenberg and Dr. Belldegrun in the mid-1980s. Dr. Belldegrun became a research fellow for Dr. Rosenberg at the cancer institute in 1985. Credit Kite Pharma

The debate goes squarely to one of the nation's most vexing challenges: rising health care and drug prices. Kite is one of a growing number of drug and biotech companies relying on federal laboratories. Analysts expect the company to charge at least $200,000 for the new treatment, which is intended as a one-time therapy for patients.

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Photo

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Photo

Dr. Belldegrun, center, at the Nasdaq stock exchange, where Kite Pharma is listed. The company was founded in 2009 and went public in 2014. Credit Nasdaq, 2016

When the fellowship ended in 1988, Dr. Belldegrun became a prominent surgeon at the University of California, Los Angeles, but the two men stayed in touch. Eventually, Dr. Belldegrun, 67, got the entrepreneurial bug. He co-founded a biotech company, Agensys, which was acquired by a bigger company for more than $500 million. He was also involved with Cougar Biotechnology, which developed the prostate cancer drug Zytiga and was acquired by Johnson & Johnson for $1 billion in May 2009. A month later, Dr. Belldegrun formed Kite with a group of colleagues and investors to pursue cancer immunotherapy.

That same month, a Florida marine contractor named Eric Karlson, whose non-Hodgkin's lymphoma was advancing despite four prior treatments, became the first patient treated by Dr. Rosenberg with what would eventually become KTE-C19. The treatment entailed removing some of Mr. Karlson's immune system T cells from his blood, genetically engineering them to recognize and fight his cancer, multiplying the T cells to huge numbers in the laboratory and transferring them back into his body. After two such treatments, Mr. Karlson remains alive and cancer-free eight years later.

Kite initially thought it would pursue an approach to immunotherapy known as cancer vaccines, but in 2010, Dr. Belldegrun visited Dr. Rosenberg and was shown the X-rays of Mr. Karlson and of a second patient.

Dr. Belldegrun was bowled over. "I had no doubt that this is going to be a drug and, more than that, it will become a platform for multiple products," he recalled. "We never looked back."

Over the next two years, the National Cancer Institute worked out a deal with Kite that was signed in 2012. It was the first of eight contracts between the government and the company that generally take two forms.

In one type of contract, Kite licenses patented inventions and agrees to pay the government royalties, roughly 5 percent of sales of any commercial product arising from a particular patent. However, there is no such license specifically for KTE-C19 because the underlying treatment was not patented by the N.C.I., so royalties will be minimal.

Officials say the agency did not apply for a patent because the treatment was similar to what others had been developing. Also, at the time the treatment was first created, in 2007, immunotherapy was considered to have dim commercial prospects.

"Back then, we didn't even think about commercial aspects," said Dr. James N. Kochenderfer, a scientist at the agency who designed the treatment when working in Dr. Rosenberg's group.

Under the second type of contract, known as a cooperative research and development agreement, Kite provides money to the N.C.I. to support research. Kite is now paying $3 million a year to Dr. Rosenberg's lab and has provided $7.5 million to it in total since 2012. Based on its regulatory filings, Kite is paying $7.8 million a year for research agreements and licenses in total, with at least $4 million of that going to the cancer institute and the rest to academic or corporate partners.

The taxpayer has invested, too. Dr. Rosenberg estimated that the government has spent roughly $10 million over the years on what has become KTE-C19. He said Kite's $3 million a year is about equal to the taxpayer funding in that area and has helped speed research.

These days, researchers from Kite and the cancer institute, typically including Dr. Rosenberg and Dr. Belldegrun, confer by conference call every other Thursday for 90 minutes. Kite employees have spent long periods at the N.C.I., learning how to manufacture the therapy and how to treat patients in advance with chemotherapy.

"We shouldn't underestimate the value and the importance of N.I.H., not only to Kite but to the whole field of engineered T-cell therapy," Dr. Belldegrun said. When Kite signed its first deal with the cancer agency, he said, it “tapped into six years of monumental work that they had done.”

Some immunotherapy competitors marvel at the company’s coup in tapping into the agency’s expertise. “They got 20 years of research all together in one scoop,” said Dr. Carlos Paya, chief executive of Immune Design, which is pursuing a different approach.

But government officials say few, if any, other companies were interested in the technology at the time Dr. Belldegrun came calling. Dr. Rosenberg said that before Kite, a few companies, including Johnson & Johnson, had looked at an earlier version of his technology but were wary because treatment involved processing each patient’s cells.

Government-developed technology available to be licensed to companies is posted on the website of the National Institutes of Health. And when the agency intends to grant a license to a particular company, it publishes that in the Federal Register, inviting public comment and possible competing offers. Both steps were taken in the case of Kite, officials said.

Kite did not get everything the cancer institute has developed in the field. Some other companies, including Opus Bio and Bluebird Bio, got rights to some products, in part because the companies had special expertise that the agency’s researchers desired. But Kite seems to have gotten the balance of them and N.C.I. technology accounts for the majority of its pipeline of possible products, though the company is diversifying.

Photo

The linked image cannot be displayed. The file may have been moved, renamed, or deleted. Verify that the link points to the correct file and location.

A slide that Kite Pharma used in presentations to potential investors pointed out the company's relationship with Dr. Rosenberg.

Dr. Rosenberg professes no interest in the business side of the Kite relationship. He does not own stock in any company, even Kite, though he could get up to $150,000 a year in patent royalties if some of Kite's efforts pay off.

Dr. Belldegrun, in contrast to his mentor, has commercial flair. He is known for his sharp business suits, lives in the Bel-Air neighborhood of Los Angeles, and seems as comfortable on Wall Street or in high society as in the operating room.

Kite's relationship with the N.C.I. is an important part of its appeal to investors. In some presentations, Dr. Belldegrun has shown a photograph of himself with Dr. Rosenberg in their younger days. And he persuaded Dr. Rosenberg to speak at Kite's first big meeting for investors in June 2015, the only time he has ever spoken to Wall Street.

In emails obtained through a Freedom of Information Act request by Knowledge Ecology International, Dr. Belldegrun praised Dr. Rosenberg's talk and sent him copies of investment reports from the conference written by Wall Street analysts.

"Thank you for making the effort to come to NY," Dr. Belldegrun wrote. "I heard only raving reviews about your presence and presentation."

A 'Reasonable' Question

The reliance of private companies on government-funded research goes well beyond obvious cases like Kite. In many instances, companies work with universities or medical centers that, in turn, have been funded from the $32 billion annual budget of the National Institutes of Health.

Kite's two main competitors, Novartis and Juno Therapeutics, for instance, derived similar immunotherapy treatments largely from academic institutions, developed at least in part with government funding. Novartis has a relationship with the University of Pennsylvania, and Juno with the Memorial Sloan Kettering Cancer Center, the Fred Hutchinson Cancer Research Center and Seattle Children's Hospital.

"For the most important drugs you'll see some public-sector involvement," said Bhaven Sampat, an associate professor of health policy and management at Columbia University. He was one author of a study that found that 9 percent of all drugs approved between 1988 and 2005 were based directly on a patent held by the public sector. But 47.8 percent of the drugs relied at least indirectly on some federally funded research.

Continue reading the main story
Photo

The linked image cannot be displayed. The file may have been moved, renamed, or deleted. Verify that the link points to the correct file and location.

Eric Karlson at his home on Marco Island, Fla., this month. Mr. Karlson's non-Hodgkin's lymphoma was successfully treated by Dr. Rosenberg with what would eventually become KTE-C19. Credit Scott McIntyre for The New York Times

The figures were higher for more medically important drugs: 17.4 percent had a direct public-sector patent, while 64.5 percent had at least an indirect public-sector influence.

These figures are up sharply from before the 1980s. Such partnerships and licensing deals were encouraged by the 1980 Bayh-Dole and Stevenson-Wydler Acts, and the 1986 Federal Technology Transfer Act. The laws are credited with jump-starting the biotechnology industry.

But from the beginning, some people questioned whether taxpayers were getting a bad deal.

Perhaps the best-known drug developed from a cooperative research and development agreement — the cancer drug Taxol — was the subject of several congressional hearings in the early 1990s that investigated whether the drug's maker, Bristol-Myers Squibb, charged too much and whether the government recouped enough of its investment. In the end, the pricing was left unchanged.

The N.I.H. argues that if it imposes pricing restrictions, it won't get partners. In fact, in 1995, it struck from its negotiating tactics a goal that prices be "reasonable."

"Companies will not take technologies from us if we say the government will decide in the future what the price will be," said Mark Rohrbaugh, who ran the technology transfer office at the institutes from 2001 to 2013 and is now an adviser to the agency. After the "reasonable price" clause was struck, he said, there was a threefold increase in partnership deals.

The N.I.H. can collect royalties from successful products to help offset the costs of the research, but so far these royalties have been small, amounting to an estimated $135 million in the last fiscal year from 870 licenses, with the bulk of the money coming from a small number of drugs.

“We’re not preoccupied with financial value,” Dr. Rohrbaugh said. “Our mission is treatment of people and improving public health.”

In that regard, the government’s bet on a small company like Kite, which might have seemed risky, appears to be paying off so far. Dr. Belldegrun has largely delivered on promises to raise money, assemble an experienced staff, build the factory, conduct clinical trials and begin to apply for regulatory approval. Once considered the underdog to Novartis and Juno, Kite might be the first reach the market.

Photo

Scans of Mr. Karlson’s body before and after his treatment. In the cross-sections on the left, the arrows point to signs of lymphoma in areas such as his armpits, chest, spleen and pelvis. Credit National Cancer Institute

Academic centers and companies often drive harder bargains in licensing technology. In some cases, academic centers own a stake in a company they license technology to, allowing them to reap a financial windfall if the company does well. Both the Hutchinson cancer center and Sloan

Kettering have owned stock in Juno and are entitled to substantial payments — up to $350 million and $150 million — if Juno's stock reaches certain levels.

The N.I.H. does not take equity positions in companies to avoid an appearance of a conflict of interest. So to critics of the government deals, drug prices are crucial to understanding taxpayer value. After all, they ask, is a drug truly widely available — which is what the government says is its measure of success — if it costs too much for some people?

Rachel Sachs, an associate law professor at Washington University in St. Louis and expert in innovation policy, said the government had every right to seek price concessions. She noted that the government, through Medicare and Medicaid, was effectively buying its inventions back from itself. "The public is paying for the research and to the extent that many people, if not most, will pay through public insurance, we're paying again," she said.

Hillary Clinton, in her campaign for president, promised to set new rules for federal support of research so that Americans "get the value they deserve" for the money taxpayers spend in supporting research. It is not clear how President-elect Donald J. Trump will approach these issues; he has said he favors reducing health care costs, but Republicans, who control Congress, too, have opposed government involvement in price setting.

One mechanism to control pricing already exists. It is called march-in rights, and it lets the N.I.H. take back control of a patent on an invention made with federal funding if the drug is not being made available to the public on reasonable terms. The tool has gone unused.

Earlier this year, Knowledge Ecology International and another advocacy group, the Union for Affordable Cancer Treatment, petitioned the agency to exercise march-in rights on Xtandi, a prostate cancer drug that was developed by federally funded researchers at U.C.L.A. It said the price in the United States of about $129,000 a year, two to four times that in other developed countries, meant the drug was not reasonably available. The effort was supported by other public interest groups and some Democratic members of Congress.

U.C.L.A. made more than $500 million by selling its royalty rights to the drug. But the N.I.H. declined to exercise its march-in rights on Xtandi, arguing that it was not qualified to judge whether a drug's price is reasonable and that a high price does not mean a drug is not being made available to the public.

"N.I.H. has made it clear that its job is not to decide prices of drugs, period," Dr. Rohrbaugh said

Kite says it has not decided what to charge for KTE-C19, but Dr. Belldegrun hinted that Kite's therapy might be relatively expensive because ideally it would be a single treatment that would cure the patient, not a drug that would have to be taken continuously. He added that Kite would take steps to make sure that everyone who needed the drug could get it.

Meantime, the relationship between Kite and the National Cancer Institute is expanding to develop treatments for other cancers, including one technique Dr. Rosenberg thinks could be used to attack solid tumors like colon, breast and lung cancer.

"The potential for broad applicability is huge," he said.

That could mean many lives saved and maybe more billion-dollar drugs for Kite and its investors, with the American taxpayer right in the middle of the deal.

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From: Lambertson, David (NIH/NCI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=3C95B34F709746A8A2553CE54E74ACE2-LAMBERTSOND]
Sent: 8/23/2017 11:56:53 AM
To: Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]
Subject: Responses to Objecting Comments for A-381-2017
Attachments: Prospective Grant of Exclusive Patent License: The Development of a Bispecific, Biparatopic Antibody-Drug Conjugate to GPC3 for the Treatment of Human Liver Cancers to Salubris Biotherapuetics; Exclusive Patent License to Salubris Biotherapeutics, Inc.; Prospective Grant of Exclusive Patent License; Re: Prospective Grant of Exclusive Patent License: The Development of a Bispecific, Biparatopic Antibody-Drug Conjugate to GPC3 for the Treatment of Human Liver Cancers; Prospective Grant of Exclusive Patent License: Development of a Bispecific, Biparatopic Antibody-Drug Conjugate to GPC3 for the Treatment of Human Liver Cancers; Comment on "Prospective Grant of Exclusive Patent License: The Development of a Bispecific, Biparatopic Antibody-Drug Conjugate to GPC3 for the Treatment of Human Liver Cancers"; Proposed Exclusive Patent License to Salubris Biotherapeutics

Good morning Mark,

The fifteen (15) day period for objections to the Notice of Intent to Grant for license application A-381-2017 ended last night. There were eight (8) total objections, seven (7) of which were in the form of comments (the eighth was a competing application which will be analyzed and addressed separately in a Final Determination). I have attached the objecting comments that I received to this e-mail for your review. Here is a list of the commenters in order of the date of their submission, for ease of reference:

1) Knowledge Ecology International (KEI)
2) Samer Nuwayhid
3) David Kolstedt
4) Bruce Korb
5) Arnold Shugarman
6) Brinsley Davis
7) Paul Stumpf

Richard wanted me to contact you about providing formal responses to the objecting comments concerning our advertisement of intent to grant, particularly in view of the recent article concerning the intent to grant. My initial thought is b5

b5

b5 and send each to your attention for review and comment prior to sending them.

Thanks,
Dave

David A. Lambertson, Ph.D.
Senior Technology Transfer Manager
Technology Transfer Center
National Cancer Institute/NIH
david.lambertson@nih.gov
http://ttc.nci.nih.gov/

9609 Medical Center Drive, Rm 1-E530 MSC 9702
Bethesda, MD 20892-9702 (USPS)
Rockville, MD 20850-9702 (Overnight/express mail)
Phone (Main Office): 240-276-5530
Phone (direct): b6
Fax: 240-276-5504

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From: b6
on behalf of Jamie Love [james.love@keionline.org]
Sent: 8/8/2017 11:55:55 AM
To: Lambertson, David (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3c95b34f709746a8a2553ce54e74ace2-lambertsond]; Diane Singhroy [diane.singhroy@keionline.org]; Manon Ress [manon.ress@keionline.org]
Subject: Prospective Grant of Exclusive Patent License: The Development of a Bispecific, Biparatopic Antibody-Drug Conjugate to GPC3 for the Treatment of Human Liver Cancers to Salubris Biotherapuetics
Attachments: Salubris-8August2017.pdf

Dear Dr. Lambertson,

Attached are the comments of KEI on the license to Salubris Biotherapuetics.

Could we do a call about this license. Diane thinks this technology is quite important, and the patent portfolio appears to be extensive.

Jamie

--
James Love. Knowledge Ecology International
http://www.keionline.org/donate.html
KEI DC tel: +1.202.332.2670, US Mobile: +b6, Geneva Mobile: b6
twitter.com/jamie_love

KEI
KNOWLEDGE ECOLOGY
INTERNATIONAL

August 8, 2017

David A. Lambertson, Ph.D.,
Senior Licensing and Patenting Manager,
NCI Technology Transfer Center,
9609 Medical Center Drive, RM 1E530 MSC 9702,
Bethesda, MD 20892-9702 (for business mail),
Rockville, MD 20850-9702;
Telephone: (240) 276-6467;
Email: david.lambertson@nih.gov

Re: Prospective Grant of Exclusive Patent License: The Development of a Bispecific, Biparatopic Antibody-Drug Conjugate to GPC3 for the Treatment of Human Liver Cancers to Salubris Biotherapuetics, Inc.

Document Citation:, 82 FR 36808

Dear Dr. Lambertson,

We are writing regarding the notice published in the federal register, regarding a proposed exclusive worldwide license on a portfolio of patents relating to a bispecific, biparatopic antibody-drug conjugate (ADC) having: (1) The CDR sequences of both the hYP7 and HN3 anti-GPC3 monoclonal antibodies; and (2) a microtubule inhibitor payload including, but not limited to, auristatin and mertansine; for the treatment of human liver cancer.

KEI offers the following observations on the potential medical benefits of the technology.

Therapeutic antibodies have revolutionized therapy for cancer and autoimmune diseases. First monoclonal antibodies were used to target a single epitope on malignant cells, or harmful protein. Antibodies were then rendered more potent by conjugating cytotoxic molecules to them. As our understanding of the immune system is improving, we can now use antibodies to activate our lymphocytes against tumor cells. Breakthroughs in recombinant DNA technology and sequencing have enabled scientists to design multispecific antibodies that can target more than one epitope on the same or different antigen. This new generation of antibodies are effectively multi-tools with each Fv performing a different function. For example, bispecific antibodies can on one hand bind to receptors overexpressed on tumor cells and also increase internalization (for drug delivery) or trigger cell death. Some bispecific antibodies, such as BiTEs, can link effector T-cells to cancer cells. The considered license describes two paratopes that could be engineered within one antibody to target liver cancer cells. Not only would this improve the specificity of the antibody drug conjugate, but it could also inhibit growth in these cancer cells. Many bispecific antibodies are already in clinical trials and several are already on the market. The versatility of these next generation antibodies makes them highly effective therapeutic agents.

According to the Federal Register notice, the license is to Salubris Biotherapeutics, Inc. (Salubris), located in Gaithersburg, Maryland.

We have seven questions about the proposed license:

> Question 1. Is Salubris Biotherapeutics Inc. a subsidiary of Shenzhen Salubris Pharmaceuticals, a Chinese company headed by the billionaire Ye Chenghai, headquartered in Futian District, Shenzhen, Guangdong? (http://www.salubris.cn/ch/)
>
> Question 2. What is the term of the proposed license?
>
> Question 3. What is the proposed royalty on the license?
>
> Question 4. How much money did the NIH or other federal agencies spend to develop this technology?
>
> Question 5. Will the NIH or any other federal agency be subsidizing the future development of this technology in any way, and if so, how?
>
> Question 6. What terms have the NIH included in the license to ensure that a product based upon the patented invention will be “available to the public on reasonable terms,” as is required by the Bayh-Dole Act?
>
> Question 7. Did the NIH undertake any economic analysis to ensure that the terms of the license are consistent with the requirements of 35 USC 209, particularly as regards to ensuring “the proposed scope of exclusivity is not greater than reasonably necessary to provide the incentive for bringing the invention to practical application”?

Reserving the right to ask additional questions or make additional comments, KEI proposing the following issues be addressed in any license agreement:

1) [The party obtaining the license] agrees to disclose the steps it will take to enable the registration and availability of the product at an affordable price in every county with a demonstrated need, either by supplying a country directly at an

affordable, publicly disclosed price and with sufficient quantities, or by providing technology transfer and rights to all intellectual property necessary for third parties to do so; and

2) [The party obtaining the license] agrees to make the product available to the public in the U.S. at publicly disclosed prices no higher than the median price charged in Canada plus the seven countries with the largest GDP, which have per capita incomes of at least half that of the U.S.

3) [The party obtaining the license] agrees to make a available a report every year that will be made available to the public, waiving all claims of confidentiality, that provides the following information:

   a) Outlays on R&D spending on products the use the licensed invention, including separately spending on each clinical trial separately,
   b) The average and marginal costs of manufacturing products based upon the licensed invention,
   c) The total number of units and revenue of sales in every country where the product is registered and sold,
   d) The royalties paid in that period to the NIH for use of the invention,
   e) Any subsidies for R&D received from any government or charity, or any tax credits relating to the development and distribution of the products.
   f) All outlays relating to marketing the product,
   g) All outlays relating to legal issue or governmental affairs, including lobbying activities.

4) [The party obtaining the license] agrees to make available the following to any generic drug manufacturer seeking marketing approval for any small molecule and biologic product in any OECD country or for WHO prequalification for any biologic drug or vaccine:
   a) Materials:,
      i) Cellular clones and hybridoma stocks
      ii) Plasmids, plasmid maps, and sequences of antibody complementarity determining regions (CDR)
      iii) Physicochemical/ biophysical characterization
   b) Methods:
      i) Growth conditions and protocols
      ii) Attenuation or inactivation protocols
      iii) Extraction and purification protocols
      iv) Synthetic work-up and schemes
   c) sufficient quantities of the approved medication for a generic developer's testing; and to

d) allow the developer to join, a single, shared system of elements to assure safe use (ETASU) of the medication.

In previous comments, the NIH has rejected our proposals on transparency, citing 35 USC 209(f) as the rationale. This statute reads as follows:

> (f) Plan.—No Federal agency shall grant any license under a patent or patent application on a federally owned invention unless the person requesting the license has supplied the agency with a plan for development or marketing of the invention, except that any such plan shall be treated by the Federal agency as commercial and financial information obtained from a person and privileged and confidential and not subject to disclosure under section 552 of title 5.

KEI notes that 35 USC 209(f) only relates to "a plan for development or marketing of the invention" that is provided to an agency during negotiations on a license. That is different from reports that a license holder can and should make to provide the public with information on how a drug company invests in and markets a product under an exclusive license, the subsidies involved in that development, or the know-how and materials that are shared in order to make generic markets more competitive once the exclusive term of the license concludes.

Sincerely,

James Love
Director
Knowledge Ecology International
1621 Connecticut Avenue, Suite 500
Washington, DC 20009
james.love@keionline.org
+1.202.332.2670

Diane Singhroy
Scientific and Technical Advisor
Knowledge Ecology International

From: Samer Nuwayhid b6
Sent: 8/8/2017 8:04:24 PM
To: Lambertson, David (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3c95b34f709746a8a2553ce54e74ace2-lambertsond]
Subject: Exclusive Patent License to Salubris Biotherapeutics, Inc.

Hi Dr. Lambertson,
As a former NCI employee and current employee in biotech, I am writing to express my concerns and dislike, in regards to awarding an exclusive patent to Salubris. I disagree awarding exclusive patent license from tax-payer research to a foreign company, with no controls over pricing of the drug. Were companies in the United States, given the opportunity to compete for this exclusive patent license? In addition, why is the NIH doing this in total secrecy without feedback from the general public.
I think it is time to hold public hearings on NIH licensing practices, so we as tax-payers are not left in the dark.
Thank you for your time.

Regards,
Samer Nuwayhid

From: David Kolstedt b6
Sent: 8/9/2017 3:35:32 PM
To: Lambertson, David (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3c95b34f709746a8a2553ce54e74ace2-lambertsond]
Subject: Prospective Grant of Exclusive Patent License

I read the Huffington Post article that this license does not specify pricing obligations whatsoever. If US taxpayer dollars were used to develop the solution, then US taxpayers should benefit.

The license should contain a maximum price formula for US citizens before it is granted. I do not know enough details to specify what that formula should be but there should be a maximum price charged.

Please add this to the comments section of the NIH comments. I could not do this on-line.

Thanks for your attention,
David Kolstedt
b6

From: Bruce Korb b6
Sent: 8/10/2017 2:53:37 PM
To: Lambertson, David (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3c95b34f709746a8a2553ce54e74ace2-lambertsond]
Subject: Re: Prospective Grant of Exclusive Patent License: The Development of a Bispecific, Biparatopic Antibody-Drug Conjugate to GPC3 for the Treatment of Human Liver Cancers

Good morning Mr. Lambertson,

I am a cranky citizen who does not like to pay for research only to have the benefits of that research handed over to a private company for its exclusive benefit. What I am trying to understand is the rationale for doing so. Is the government making sure that in handing off that intellectual property that it is getting the best return for the research investment? What value is the private company giving the government for that research? Is it in the best interests of the citizenry to have a company hold exclusive patent rights and charge whatever it can get for the medicine?

So, indeed, I am not interested in the pharmacology of the drug. I likely would not understand. I am interested in the process used to get to where we are. Especially the part that made it difficult for people to comment on the proposal.

Thank you.
Regards, Bruce

On Thu, Aug 10, 2017 at 4:38 AM, Lambertson, David (NIH/NCI) [E]
<david.lambertson@nih.gov> wrote:
> Good morning Mr. Korb,
>
> Thank you for your e-mail. So that I may answer your e-mail appropriately, I must ask for a clarification. Is this a request for a copy of the patent/patent application, and is that the information about which you are asking why it is not available online?
>
> When I have your answers, I will prepare a response.
>
> Thank you,
>
> David A. Lambertson, Ph.D.
> Senior Technology Transfer Manager
> Technology Transfer Center
> National Cancer Institute/NIH
> david.lambertson@nih.gov
> http://ttc.nci.nih.gov/
>
> 9609 Medical Center Drive, Rm 1-E530 MSC 9702
> Bethesda, MD 20892-9702 (USPS)
> Rockville, MD 20850-9702 (Overnight/express mail)
> Phone (Main Office): 240-276-5530
> Phone (direct): (240) 276-6467
> Fax: 240-276-5504
>
> Note: This email may contain confidential information. If you are not the intended recipient, any disclosure, copying or use of this email or the information enclosed therein is strictly prohibited, and you should notify the sender for return of any attached documents
>
> -----Original Message-----
> From: Bruce Korb [mailto: b6
> Sent: Wednesday, August 09, 2017 4:38 PM
> To: Lambertson, David (NIH/NCI) [E] <david.lambertson@nih.gov>
> Subject: Prospective Grant of Exclusive Patent License: The Development of a Bispecific, Biparatopic Antibody-Drug Conjugate to GPC3 for the Treatment of Human Liver Cancers
>
> Requests for copies of the patent applications, inquiries, and comments relating to the contemplated Exclusive Patent License should be directed to: David A. Lambertson, Ph.D., Senior Licensing and Patenting Manager, NCI Technology Transfer Center, 9609 Medical Center Drive, RM 1E530 MSC 9702, Bethesda, MD 20892-9702 (for business mail), Rockville, MD 20850-9702; Telephone: (240) 276-6467; Email:
> david.lambertson@nih.gov.
>
> Also, please explain why the information is not online and responses are not submissable online. Thank you.

```
>
>   - Bruce Korb
>          b6
>
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 - Bruce
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From: Arnold Shugarman b6
Sent: 8/10/2017 1:01:23 AM
To: Lambertson, David (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3c95b34f709746a8a2553ce54e74ace2-lambertsond]
CC: senator@feinstein.senate.gov
Subject: Prospective Grant of Exclusive Patent License: Development of a Bispecific, Biparatopic Antibody-Drug Conjugate to GPC3 for the Treatment of Human Liver Cancers

I oppose giving an exclusive patent license to Salubris Biotherapeutics, Inc. for this drug.

If this drug was developed by NIH with taxpayers' funds, no company should be given a license to profit exclusively on this or any drug. Any agreement made by NIH or any other federal agency on drugs developed with public funding should include a profit sharing agreement with the Federal government (taxpayers).

Further, the agreement should be structured so that the price of any drug that results from granting the patent should be fair and reasonable. At the very least, the price should be set so that the drug company cannot charge American consumers more than the lowest price negotiated world-wide for the drug.

In sum, funds from American taxpayers should not be used to enrich private enterprises. It's time that Americans get a fair return on their investment of tax dollars.

Arnold Shugarman
b6

From: b6
Sent: 8/10/2017 2:20:04 PM
To: Lambertson, David (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3c95b34f709746a8a2553ce54e74ace2-lambertsond]
Subject: Comment on "Prospective Grant of Exclusive Patent License: The Development of a Bispecific, Biparatopic Antibody-Drug Conjugate to GPC3 for the Treatment of Human Liver Cancers"

Hello, Dr. lambertson,
I have just read about this licensing proposal and I find it reckless to grant exclusive rights without ensuring that Americans will be able to buy the resulting product at a fair price. That is a bad deal for America!
You know healthcare costs are skyrocketing. You know prescrition drug costs in this country are out of control. Why would the NIH do something that exacerbates these situations?
Please reconsider this deal.
Sincerely,
Brinsley Davis
Concerned Minnesota resident, zip code b6

From: Paul Stumpf b6

Sent: 8/17/2017 7:20:56 PM

To: Lambertson, David (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3c95b34f709746a8a2553ce54e74ace2-lambertsond]

Subject: Proposed Exclusive Patent License to Salubris Biotherapeutics

Dear Dr. Lambertson - I am concerned by what I have read about the proposed Exclusive Patent License proposed to be granted to Salubris - with both the terms of the license and the fact that Salubris is ultimately controlled by a wealthy Chinese. I have these concerns despite the fact that Salubris is in Gaithersburg, so that as a Maryland resident I might arguably benefit from its getting this license.

As with the proposed Zika license, I don't get giving away the benefits of taxpayer-funded research to anyone, and especially to foreign-controlled entities.

Paul Stumpf
b6

From: Baker, Rebecca (NIH/OD) [E] [/O=NIH/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BAKERRG]
Sent: 4/7/2016 2:16:29 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=OD/cn=ROHRBAUM]; Marshall, Lisa (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=OD/cn=SchwartzL]
CC: Plude, Denise (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=Recipients/cn=parksde]; Carr, Sarah (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=OD/cn=CARRS]; Wolinetz, Carrie (NIH/OD) [E] [/O=NIH/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=Wolinetzcdc9a]
Subject: RE: Xtandi letter (fr KEI)

Hi Lisa,

Correct, we have spoken with OS and they will not clear the Xtandi response, b5

b5

Thanks,
Rebecca

From: Rohrbaugh, Mark (NIH/OD) [E]
Sent: Thursday, April 07, 2016 10:13 AM
To: Marshall, Lisa (NIH/OD) [E] <MarshallL@od.nih.gov>
Cc: Plude, Denise (NIH/OD) [E] <pludede@mail.nih.gov>; Carr, Sarah (NIH/OD) [E] <CarrS@OD.NIH.GOV>; Wolinetz, Carrie (NIH/OD) [E] <carrie.wolinetz@nih.gov>; Baker, Rebecca (NIH/OD) [E] <bakerrg@od.nih.gov>
Subject: Fwd: Xtandi letter (fr KEI)

b5

b5 Do you know Rebecca?

Sent from my iPhone

Begin forwarded message:

> **From:** "Marshall, Lisa (NIH/OD) [E]" <MarshallL@od.nih.gov>
> **Date:** April 7, 2016 at 10:04:29 AM EDT
> **To:** "Rohrbaugh, Mark (NIH/OD) [E]" <RohrBauM@OD.NIH.GOV>
> **Cc:** "Plude, Denise (NIH/OD) [E]" <pludede@mail.nih.gov>, "Carr, Sarah (NIH/OD) [E]" <CarrS@OD.NIH.GOV>
> **Subject: FW: Xtandi letter (fr KEI)**
>
> Hi Dr. Rohrbaugh,
> Here are clearance comments from OGC on the Xtandi march-in letter. b5
> b5 Sorry about my confusion. b5
>
> b5

From: Chang, Kevin (NIH/NCI) [E] [/O=NIH/OU=EXTERNAL (FYDIBOHF25SPDLT)/CN=RECIPIENTS/CN=EC1C6145EC1648F3B642215B9E72B16A]
Sent: 6/6/2017 7:40:35 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=OD/cn=ROHRBAUM]
Subject: FW: RE: Prospective Grant of Exclusive Patent License: Chimeric L1/L2 Protein and Virus-Like Particles Based Human Papillomavirus Vaccines

Hi Mark,

Just wanted to let you know that KEI sent comments for my Intent to Grant Federal Register Notice. Please see the emails below. The federal register notice is in the following link.

https://www.federalregister.gov/documents/2017/05/19/2017-10153/prospective-grant-of-exclusive-patent-license-chimeric-l1l2-protein-and-virus-like-particles-based

Best,

Kevin

Kevin W. Chang, Ph.D.
Senior Technology Transfer Manager
NCI Technology Transfer Center
9609 Medical Center Dr.
Room 3W-128, MSC 9702
Rockville, MD 20850-9702
Phone: 240-276-6910
Email: changke@mail.nih.gov

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From: Rodriguez, Richard (NIH/NCI) [E]
Sent: Tuesday, June 06, 2017 3:29 PM
To: Chang, Kevin (NIH/NCI) [E] <changke@mail.nih.gov>
Subject: RE: RE: Prospective Grant of Exclusive Patent License: Chimeric L1/L2 Protein and Virus-Like Particles Based Human Papillomavirus Vaccines

Yes

From: Chang, Kevin (NIH/NCI) [E]
Sent: Tuesday, June 06, 2017 2:48 PM
To: Rodriguez, Richard (NIH/NCI) [E] <richard.rodriguez@nih.gov>
Subject: FW: RE: Prospective Grant of Exclusive Patent License: Chimeric L1/L2 Protein and Virus-Like Particles Based Human Papillomavirus Vaccines

Hi Richard,

Just wanted to let you know that I received comments from KEI from my intent to grant Federal Register notice. Should I also forward this to Mark, so he is aware of this?

Kevin W. Chang, Ph.D.
Senior Technology Transfer Manager
NCI Technology Transfer Center
9609 Medical Center Dr.
Room 3W-128, MSC 9702
Rockville, MD 20850-9702
Phone: 240-276-6910
Email: changke@mail.nih.gov

The attached information may be confidential. It is intended only for the addressee(s) identified above. If you are not the addressee(s), or an employee or agent of the addressee(s), please note that any dissemination, distribution, or copying of this communication is strictly prohibited. If you have received this email in error, please destroy the document and notify the sender of the error. Thank you.

From: b6 **On Behalf Of** Jamie Love
Sent: Monday, June 05, 2017 4:25 PM
To: Chang, Kevin (NIH/NCI) [E] <changke@mail.nih.gov>
Cc: Manon Ress <MANON.RESS@cancerunion.org>
Subject: RE: Prospective Grant of Exclusive Patent License: Chimeric L1/L2 Protein and Virus-Like Particles Based Human Papillomavirus Vaccines

June 5, 2017

Kevin W. Chang, Ph.D.
Senior Technology Transfer Manager
NCI Technology Transfer Center
9609 Medical Center Drive,
RM 1E530 MSC 9702
Bethesda, MD 20892-9702
Telephone: (240)-276-6910;
Facsimile: (240)-276-5504;

Via Email: changke@mail.nih.gov.

RE: Prospective Grant of Exclusive Patent License: Chimeric L1/L2 Protein and Virus-Like Particles Based Human Papillomavirus Vaccines

We are writing in response to the notice in 82 FR 23012

, regarding the possible grant of an exclusive license to PathoVax, LLC located in Baltimore, MD

for
patents relating to
Chimeric L1/L2 Protein and Virus-Like Particles Based Human Papillomavirus Vaccines
.

It is our understanding that PathoVax is a very small start-up, that has been funded by the NIH and a handful of investors. We would like to know the extent of the NIH funding of the firm, prior to the license, and also the extent to which the US government will be funding the clinical trials related to the licensed patents.

We are particularly interested in this human papillomavirus (HPV) vaccine

, because the costs of the existing vaccines have been high, and access has been limited, both in the United States and elsewhere.

In the past, exclusive licenses of federally funded patented related to the HPV vaccines have created unfortunate barriers to the development of vaccines that protect against the widest range of HPV strains.

According the NIH [1] , HPVs causes several types of cancer, including:

- **Cervical cancer:** Virtually all cases of cervical cancer are caused by HPV, and just two HPV types, 16 and 18, are responsible for about 70% of all cases (7, 8).
- **Anal cancer:** About 95% of anal cancers are caused by HPV. Most of these are caused by HPV type 16.
- **Oropharyngeal cancers (cancers of the middle part of the throat, including the soft palate, the base of the tongue, and the tonsils):** About 70% of oropharyngeal cancers are caused by HPV. In the United States, more than half of cancers diagnosed in the oropharynx are linked to HPV type 16 (9).
- **Rarer cancers:** HPV causes about 65% of vaginal cancers, 50% of vulvar cancers, and 35% of penile cancers (10). Most of these are caused by HPV type 16.

High-risk HPV types cause approximately 5% of all cancers worldwide (11). In the United States, high-risk HPV types cause approximately 3% of all cancer cases among women and 2% of all cancer cases among men (12).
The vaccine should be available and affordable to all.

Question: Has the NIH done an analysis to see of a policy of non-exclusive licensing would better serve the goals of developing vaccines with the widest range of protection for HPV strains?

As regards pricing and access, it is our view that the NIH is required under 35 USC 209 and 35 USC 201(f) to ensure that any holder of an exclusive license will make the vaccine available to the public on reasonable terms.

One condition on pricing that is essential is that the price of the vaccine in the United States be no higher than the companies charge in other high income countries. To this end, language that requires that the price of the vaccine in the United States be no more than the median price of the vaccine in the seven countries with the highest GDP and a per capita income of at least 50 percent of the US per capital income, can and should be inserted into the patent license. This is a very minimal protection for U.S. residents, who after, all, have paid for the patented invention.

Secondly, it is important to ensure that the vaccine is available at prices that are affordable in developing countries. To this end, we suggest the following language in the license agreement:

A vaccine based upon the patented inventions shall be available at prices that are affordable in countries with per capita incomes of 30 percent or less of the United States, and if the U.S. Department of Health and Human Services finds otherwise, it reserves the right to grant non-exclusive to generic vaccine manufacturers.

We requests that the license require PathoVax to provide the NIH annual reports on the R&D outlays related to the patents, including expenditures on each specific clinical trial, and annual reports providing the revenues from sales, the number of units sold, and prices per unit, and the royalties paid to the United States government, in each country where the products are commercialized, and that these reports be made public.

Sincerely,

James Love, Knowledge Ecology International
Manon Ress, PhD. Union for Affordable Cancer Treatment

[1] https://www.cancer.gov/about-cancer/causes-prevention/risk/infectious-agents/hpv-fact-sheet

--
James Love. Knowledge Ecology International
http://www.keionline.org/donate.html
KEI DC tel: +1.202.332.2670, US Mobile: b6 Geneva Mobile: b6
twitter.com/jamie_love

From: Finley, Stephen (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=884C93801BA445F68C2BA0CE4913F3C8-FINLEYS]
Sent: 8/23/2017 11:42:49 AM
To: Devany, John (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b7616e9f906f43adac8d838de12a7bf1-devanyjr]; Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]
CC: Shmilovich, Michael (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7dfe19bfd1d443ceb700b9f22d159a90-shmilovm]; Rogers, Karen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b23ef4ca2fa14a6eb174ee611953a396-rogersk]; Goldstein, Bruce (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb67e8fe5aa2452a8a7f200e5fb4335b-goldsteb]
Subject: RE: Fed Reg Objections/Responses

John,
Technically, b5
b5 I have copied Karen and Bruce as they are better suited to answer the question.

Stephen

Stephen L. Finley, Ph.D.
Senior Advisor
Phone: 301-435-4082
Email: sf31w@nih.gov

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From: Devany, John (NIH/NHLBI) [E]
Sent: Wednesday, August 23, 2017 7:35 AM
To: Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>; Finley, Stephen (NIH/OD) [E] <finleys@od6100m1.od.nih.gov>
Cc: Shmilovich, Michael (NIH/NHLBI) [E] <michael.shmilovich@nih.gov>
Subject: Fed Reg Objections/Responses

Good Morning Mark and Steve,

We have a question regarding objections/responses. b5
b5

Thank you very much,
John

From: Hammersla, Ann (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/CN=RECIPIENTS/CN=HAMMERSLAA]
Sent: 4/7/2016 6:07:03 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=OD/cn=ROHRBAUM]
Subject: RE: Xtandi letter (fr KEI)

I am now on a conference call with GAO.

From: Rohrbaugh, Mark (NIH/OD) [E]
Sent: Thursday, April 07, 2016 2:01 PM
To: Hammersla, Ann (NIH/OD) [E] <hammerslaa@mail.nih.gov>
Subject: FW: Xtandi letter (fr KEI)

I'll call in a minute

From: Rohrbaugh, Mark (NIH/OD) [E]
Sent: Thursday, April 07, 2016 10:13 AM
To: Marshall, Lisa (NIH/OD) [E] <MarshalL@od.nih.gov>
Cc: Plude, Denise (NIH/OD) [E] <pludede@mail.nih.gov>; Carr, Sarah (NIH/OD) [E] <CarrS@OD.NIH.GOV>; Wolinetz, Carrie (NIH/OD) [E] <carrie.wolinetz@nih.gov>; Baker, Rebecca (NIH/OD) [E] <bakerrg@od.nih.gov>
Subject: Fwd: Xtandi letter (fr KEI)

b5
b5 Do you know Rebecca?

Sent from my iPhone

Begin forwarded message:

> **From:** "Marshall, Lisa (NIH/OD) [E]" <MarshalL@od.nih.gov>
> **Date:** April 7, 2016 at 10:04:29 AM EDT
> **To:** "Rohrbaugh, Mark (NIH/OD) [E]" <RohrBauM@OD.NIH.GOV>
> **Cc:** "Plude, Denise (NIH/OD) [E]" <pludede@mail.nih.gov>, "Carr, Sarah (NIH/OD) [E]" <CarrS@OD.NIH.GOV>
> **Subject: FW: Xtandi letter (fr KEI)**
>
> Hi Dr. Rohrbaugh,
> Here are clearance comments from OGC on the Xtandi march-in letter. b5 b5 Sorry about my confusion. b5
> b5

From: Fine, Amanda (NIH/OD) [E] [/O=NIH/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=FINEAB]
Sent: 6/7/2017 7:50:47 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=OD/cn=ROHRBAUM]
CC: Myles, Renate (NIH/OD) [E] [/O=NIH/OU=Nihexchange/cn=recipients/cn=mylesr]; Wojtowicz, Emma (NIH/OD) [E] [/O=NIH/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=Wojtowiczeme6d]
Subject: FW: WSJ Media Request: CRISPR patent

Hi Mark-

Amy Marcus from WSJ reached out to HHS about CRISPR patents. Please see her questions below. How would you recommend handling? Her deadline is tomorrow.

Thanks!
Amanda

From: Marcus, Amy [mailto:amy.marcus@wsj.com]
Sent: Wednesday, June 07, 2017 12:16 PM
To: OS Media (HHS/ASPA)
Subject: WSJ Media Request: Deadline story!

To the HHS Media Department:

I am a staff reporter at The Wall Street Journal, where I cover health and medicine.

I am working on an article about Crispr patents. Yesterday, June 6, 2017, Secretary Price and HHS received via email a document from the group, Knowledge Ecology International, requesting that Secretary Price and HHS develop a policy on the licensing of federally-funded CRISPR patented inventions.

I am seeking comment for a deadline story about this issue, including the document request.

1. Is there someone at HHS with whom I can speak? If not, then a comment about whether HHS has an existing policy that deals with the licensing of Crispr technology, which was developed with federal grants.

2. What is HHS's response to the request to develop a policy on the licensing of Crispr patented inventions? Is HHS currently working on such a policy, and if not, does HHS plan to create a policy regarding this issue?

I am on deadline for this article, and would need a response by Thursday morning.

Thank you.

Sincerely yours,

Amy Dockser Marcus
Staff Reporter, The Wall Street Journal
C: b6

From: Vepa, Sury (NIH/NCATS) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=25B6C29F123544738FCBAD51627B2D23-VEPAS]
Sent: 7/10/2018 6:23:35 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]; Portilla, Lili (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9b03f548be224eb9b7b6167a32e9cc4a-portilll]
Subject: FW: Who runs Apexx Oncology?

FYI

Sury

Phone: 301-827-7181
Cell: b6
E-Mail: sury.vepa@nih.gov

From: Vepa, Sury (NIH/NCATS) [E]
Sent: Tuesday, July 10, 2018 2:23 PM
To: 'James Love' <james.love@keionline.org>
Subject: RE: Who runs Apexx Oncology?

This is republication of the FR Notice published previously (82 FR 25295) and was necessitated because the GeneXion Oncology, Inc changed its name to Apexx Oncology. Thanks.

Sury Vepa

Phone: 301-827-7181
Cell: b6
E-Mail: sury.vepa@nih.gov

From: James Love [mailto:james.love@keionline.org]
Sent: Tuesday, July 10, 2018 1:16 PM
To: Vepa, Sury (NIH/NCATS) [E] <sury.vepa@nih.gov>
Subject: Who runs Apexx Oncology?

--
James Love. Knowledge Ecology International
http://www.keionline.org/donate.html
KEI DC tel: +1.202.332.2670, US Mobile: b6 Geneva Mobile: b6
twitter.com/jamie_love

From: Burke, Andy (NIH/NCI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=305E280EDC664E68939D4348603F56E6-BURKEAR]
Sent: 1/3/2019 2:57:07 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]; Lambertson, David (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3c95b34f709746a8a2553ce54e74ace2-lambertsond]
CC: Rodriguez, Richard (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8092cb5394e04733ac0d4d84d25f65e5-rodrigr]; Freel, Rose (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8ae9aab7e3249e881bb573e9a189036-freelrm]
Subject: RE: IMPORTANT: b5

Hi Mark,

b5

Thanks,

Andy

From: Rohrbaugh, Mark (NIH/OD) [E]
Sent: Wednesday, January 02, 2019 8:55 PM
To: Lambertson, David (NIH/NCI) [E] <david.lambertson@nih.gov>; Burke, Andy (NIH/NCI) [E] <andy.burke@nih.gov>
Cc: Rodriguez, Richard (NIH/NCI) [E] <richard.rodriguez@nih.gov>; Freel, Rose (NIH/NCI) [E] <rose.freel@nih.gov>
Subject: RE: IMPORTANT: b5

Thanks much. This is sufficient.

From: Lambertson, David (NIH/NCI) [E] <david.lambertson@nih.gov>
Sent: Wednesday, January 02, 2019 6:30 PM
To: Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>; Burke, Andy (NIH/NCI) [E] <andy.burke@nih.gov>
Cc: Rodriguez, Richard (NIH/NCI) [E] <richard.rodriguez@nih.gov>; Freel, Rose (NIH/NCI) [E] <rose.freel@nih.gov>
Subject: RE: IMPORTANT: b5

Hi Mark,

b4,b5

b4,b5

Dave

David A. Lambertson, Ph.D.
Senior Technology Transfer Manager
Technology Transfer Center
National Cancer Institute/NIH
david.lambertson@nih.gov
http://ttc.nci.nih.gov/

9609 Medical Center Drive, Rm 1-E530 MSC 9702
Bethesda, MD 20892-9702 (USPS)
Rockville, MD 20850-9702 (Overnight/express mail)
Phone (Main Office): 240-276-5530
Phone (direct): b6
Fax: 240-276-5504

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From: Rohrbaugh, Mark (NIH/OD) [E]
Sent: Wednesday, January 02, 2019 3:53 PM
To: Burke, Andy (NIH/NCI) [E] <andy.burke@nih.gov>
Cc: Rodriguez, Richard (NIH/NCI) [E] <richard.rodriguez@nih.gov>; Freel, Rose (NIH/NCI) [E] <rose.freel@nih.gov>; Lambertson, David (NIH/NCI) [E] <david.lambertson@nih.gov>
Subject: RE: IMPORTANT: b5

b5

b5 Don't need this today but in the next few days.

Thanks much

From: Burke, Andy (NIH/NCI) [E] <andy.burke@nih.gov>
Sent: Wednesday, January 02, 2019 3:50 PM
To: Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>
Cc: Rodriguez, Richard (NIH/NCI) [E] <richard.rodriguez@nih.gov>; Freel, Rose (NIH/NCI) [E] <rose.freel@nih.gov>;

Lambertson, David (NIH/NCI) [E] <david.lambertson@nih.gov>
Subject: RE: IMPORTANT: b5

Hi Mark,

b5

Thanks,

Andy

From: Rohrbaugh, Mark (NIH/OD) [E]
Sent: Wednesday, January 02, 2019 3:01 PM
To: Rodriguez, Richard (NIH/NCI) [E] <richard.rodriguez@nih.gov>; Freel, Rose (NIH/NCI) [E] <rose.freel@nih.gov>; Lambertson, David (NIH/NCI) [E] <david.lambertson@nih.gov>; Burke, Andy (NIH/NCI) [E] <andy.burke@nih.gov>
Cc: Berkley, Dale (NIH/OD) [E] <BerkleyD@OD.NIH.GOV>
Subject: IMPORTANT: b5
Importance: High

b5

Thanks,
Mark

Mark L. Rohrbaugh, Ph.D., J.D.
Special Advisor for Technology Transfer
Director, Division of Technology Transfer and Innovation Policy
Office of Science Policy
Office of the Director
National Institutes of Health

From: Vepa, Sury (NIH/NCATS) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=25B6C29F123544738FCBAD51627B2D23-VEPAS]
Sent: 7/10/2018 5:37:46 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]
CC: Portilla, Lili (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9b03f548be224eb9b7b6167a32e9cc4a-portilll]
Subject: RE: Who runs Apexx Oncology?

Thanks, your suggestion is on point. I will do as you suggest.

Sury

Phone: 301-827-7181
Cell: b6
E-Mail: sury.vepa@nih.gov

From: Rohrbaugh, Mark (NIH/OD) [E]
Sent: Tuesday, July 10, 2018 1:35 PM
To: Vepa, Sury (NIH/NCATS) [E] <sury.vepa@nih.gov>
Cc: Portilla, Lili (NIH/NCATS) [E] <portilll@mail.nih.gov>
Subject: Re: Who runs Apexx Oncology?

b5

Sent from my iPhone

On Jul 10, 2018, at 1:22 PM, Vepa, Sury (NIH/NCATS) [E] <sury.vepa@nih.gov> wrote:

> Hi Mark,
>
> Recently we have published an FR Notice for Intent to Grant Exclusive License to one of our technologies. This notice is a second publication for the same technology but necessitated by the original applicant's desire to change the name of the company before we executed the license agreement.
>
> Today is the last day to receive comments/objections and I received the below email from KEI asking "who runs the company".
>
> I would appreciate your advice on how to respond to this. Do I provide the information they are requesting?
>
> Thanks,
>
> Sury
>
> Phone: 301-827-7181
> Cell: b6
> E-Mail: sury.vepa@nih.gov
>
> **From:** James Love [mailto:james.love@keionline.org]
> **Sent:** Tuesday, July 10, 2018 1:16 PM

To: Vepa, Sury (NIH/NCATS) [E] <sury.vepa@nih.gov>
Subject: Who runs Apexx Oncology?

--
James Love. Knowledge Ecology International
http://www.keionline.org/donate.html
KEI DC tel: +1.202.332.2670, US Mobile: b6 Geneva Mobile: b6
twitter.com/jamie_love

From: Shmilovich, Michael (NIH/NHLBI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7DFE19BFD1D443CEB700B9F22D159A90-SHMILOVM]
Sent: 8/22/2017 12:34:28 AM
To: Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]
Subject: RE: Comments by KEI on Prospective Grant of Exclusive Patent License: MicroRNA Therapeutics for Treating Squamous Cell Carcinomas to miRecule, Inc.

Thank you!!!

From: Rohrbaugh, Mark (NIH/OD) [E]
Sent: Monday, August 21, 2017 16:55
To: Shmilovich, Michael (NIH/NHLBI) [E] <michael.shmilovich@nih.gov>
Subject: RE: Comments by KEI on Prospective Grant of Exclusive Patent License: MicroRNA Therapeutics for Treating Squamous Cell Carcinomas to miRecule, Inc.

Misha:

Here are a few comments I have made in your draft. Glad to hear this is going forward.
Regards,
Mark

From: Shmilovich, Michael (NIH/NHLBI) [E]
Sent: Friday, August 18, 2017 12:15 PM
To: Deutch, Alan (NIH/NHLBI) [E] <deutcha@nhlbi.nih.gov>; Reichman, Uri (NIH/NHLBI) [E] <uri.reichman@nih.gov>; Thalhammer-Reyero, Cristina (NIH/NHLBI) [E] <cristina.thalhammer-reyero@nih.gov>; Bailey, Brian (NIH/NHLBI) [E] <bbailey@nhlbi.nih.gov>
Cc: Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>
Subject: FW: Comments by KEI on Prospective Grant of Exclusive Patent License: MicroRNA Therapeutics for Treating Squamous Cell Carcinomas to miRecule, Inc.

Alan, Cristina, Uri, and Brian –
As you probably would have guessed, KEI objected to our notice of intent to grant an exclusive license to miRecule. I'm including a copy of the FR notice, KEI's comments and my draft response seeking your comments.

b5

b5

b5 Happy reading.

Regards,

Michael A. Shmilovich, Esq., CLP

NIH National Heart, Lung, and Blood Institute
Office of Technology Transfer and Development
31 Center Drive Room 4A29, MSC2479
Bethesda, MD 20892-2479
o. 301.435.5019
shmilovm@mail.nih.gov

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From: jamespackardlove@gmail.com [mailto b6] **On Behalf Of** Jamie Love
Sent: Friday, August 18, 2017 10:17
To: Shmilovich, Michael (NIH/NHLBI) [E] <michael.shmilovich@nih.gov>
Cc: Kim Treanor <kim.treanor@keionline.org>; Diane Singhroy <diane.singhroy@keionline.org>; Andrew S. Goldman <andrew.goldman@keionline.org>; Manon Ress <manon.ress@keionline.org>
Subject: Comments by KEI on Prospective Grant of Exclusive Patent License: MicroRNA Therapeutics for Treating Squamous Cell Carcinomas to miRecule, Inc.

Dear Michael Shmilovich, Esq.

Attached as a PDF file are the Comments by KEI on Prospective Grant of Exclusive Patent License: MicroRNA Therapeutics for Treating Squamous Cell Carcinomas to miRecule, Inc.

Jamie

--
James Love. Knowledge Ecology International
http://www.keionline.org/donate.html
KEI DC tel: +1.202.332.2670, US Mobile: b6 , Geneva Mobile: b6 , twitter.com/jamie_love

From: Lambertson, David (NIH/NCI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=3C95B34F709746A8A2553CE54E74ACE2-LAMBERTSOND]
Sent: 7/9/2018 5:05:11 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]
CC: Dhal, Abritee (NIH/NCI) [F] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f2d96a2cc6704aeba7574a1bbc703b7f-dhala2]; Rodriguez, Richard (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8092cb5394e04733ac0d4d84d25f65e5-rodrigr]; Whitney, Laurie (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=903a0f2d510b4ef3a081c10eef17deb8-whitneyl]
Subject: FW: Question on your CAR T clinical trial enrollment, budget and funders

Good afternoon Mark,

Richard is out of the office this week, but since we have been coordinating with you on responses to KEI anyway, I am reaching out to you directly with a copy to him.

Please see the e-mail from KEI below, forwarded from Dr. Kochenderfer. As you can see, Dr. Kochenderfer did not respond, b5
b5

Thanks,
Dave

David A. Lambertson, Ph.D.
Senior Technology Transfer Manager
Technology Transfer Center
National Cancer Institute/NIH
david.lambertson@nih.gov
http://ttc.nci.nih.gov/

9609 Medical Center Drive, Rm 1-E530 MSC 9702
Bethesda, MD 20892-9702 (USPS)
Rockville, MD 20850-9702 (Overnight/express mail)
Phone (Main Office): 240-276-5530
Phone (direct): b6
Fax: 240-276-5504

Note: This email may contain confidential information. If you are not the intended recipient, any disclosure, copying or use of this email or the information enclosed therein is strictly prohibited, and you should notify the sender for return of any attached documents

---

From: Kochenderfer, James (NIH/NCI) [E]
Sent: Monday, July 09, 2018 12:57 PM
To: Lambertson, David (NIH/NCI) [E] <david.lambertson@nih.gov>; Dhal, Abritee (NIH/NCI) [F] <abritee.dhal@nih.gov>
Subject: FW: Question on your CAR T clinical trial enrollment, budget and funders

Dave and Abritee,

I received the email below. I did not respond.

Jim

From: Luis Gil Abinader [mailto:luis.gil.abinader@keionline.org]
Sent: Monday, July 09, 2018 12:39 PM
To: Hansen, Brenna (NIH/NCI) [E] <brenna.hansen@nih.gov>; Kochenderfer, James (NIH/NCI) [E] <kochendj@mail.nih.gov>
Cc: Jamie Love <james.love@keionline.org>
Subject: Question on your CAR T clinical trial enrollment, budget and funders

Hi Brenna, James,

I'm writing on behalf of Knowledge Ecology International (KEI). KEI is currently trying to gather information on the cost of conducting clinical trials on candidates for CAR T-cell therapies, and based on our research you are the contact person for one of the clinical trials that have been conducted.

At the moment, we are trying to review information on the costs of conducting CAR T trials, in order to respond to various NIH Federal Register notices about possible exclusive license on CAR T patents owned by the NIH, as well as the Administration's request for comments on the Blueprint on pricing of drugs and other medical technologies. We also think there is a broader public interest in knowing more about R&D costs for this important technology, and one source of such information is finding out what the government is spending on the trials that the taxpayers are funding.

We would be grateful if you could provide us the following information on the CAR T-cell therapy clinical trial you conducted:

1. Total enrollment;
2. Total budget for the trial.
3. If there are other funders of the trial, such as other federal agencies, charities, businsses or other non-government entities.

Thank you in advance,

Luis Gil Abinader
luis.gil.abinader@keionline.org
(202) 332-2670

From: Berkley, Dale (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5EE461C29F5045A49F0ADF82CAAA2F31-BERKLEYD]
Sent: 1/3/2019 2:06:40 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]
Subject: RE: IMPORTANT: b5

Ok thanks. b5

b5

Dale D. Berkley, Ph.D., J.D.
Office of the General Counsel, PHD, NIH Branch
Bldg. 31, Rm. 47
Bethesda, MD 20892
301-496-6043
301-402-2528(Fax)

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From: Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>
Sent: Wednesday, January 02, 2019 8:56 PM
To: Berkley, Dale (NIH/OD) [E] <berkleyd@od.nih.gov>
Subject: FW: IMPORTANT: b5

b5

From: Lambertson, David (NIH/NCI) [E] <david.lambertson@nih.gov>
Sent: Wednesday, January 02, 2019 6:30 PM
To: Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>; Burke, Andy (NIH/NCI) [E] <andy.burke@nih.gov>
Cc: Rodriguez, Richard (NIH/NCI) [E] <richard.rodriguez@nih.gov>; Freel, Rose (NIH/NCI) [E] <rose.freel@nih.gov>
Subject: RE: IMPORTANT: b5

Hi Mark,

b4,b5

b5

Dave

David A. Lambertson, Ph.D.
Senior Technology Transfer Manager
Technology Transfer Center
National Cancer Institute/NIH
david.lambertson@nih.gov
http://ttc.nci.nih.gov/

9609 Medical Center Drive, Rm 1-E530 MSC 9702
Bethesda, MD 20892-9702 (USPS)
Rockville, MD 20850-9702 (Overnight/express mail)
Phone (Main Office): 240-276-5530
Phone (direct): b6
Fax: 240-276-5504

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From: Rohrbaugh, Mark (NIH/OD) [E]
Sent: Wednesday, January 02, 2019 3:53 PM
To: Burke, Andy (NIH/NCI) [E] <andy.burke@nih.gov>
Cc: Rodriguez, Richard (NIH/NCI) [E] <richard.rodriguez@nih.gov>; Freel, Rose (NIH/NCI) [E] <rose.freel@nih.gov>; Lambertson, David (NIH/NCI) [E] <david.lambertson@nih.gov>
Subject: RE: IMPORTANT: b5

b5

Thanks much

From: Burke, Andy (NIH/NCI) [E] <andy.burke@nih.gov>
Sent: Wednesday, January 02, 2019 3:50 PM
To: Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>
Cc: Rodriguez, Richard (NIH/NCI) [E] <richard.rodriguez@nih.gov>; Freel, Rose (NIH/NCI) [E] <rose.freel@nih.gov>; Lambertson, David (NIH/NCI) [E] <david.lambertson@nih.gov>
Subject: RE: IMPORTANT: b5

Hi Mark,

b5

b5

Thanks,

Andy

From: Rohrbaugh, Mark (NIH/OD) [E]
Sent: Wednesday, January 02, 2019 3:01 PM
To: Rodriguez, Richard (NIH/NCI) [E] <richard.rodriguez@nih.gov>; Freel, Rose (NIH/NCI) [E] <rose.freel@nih.gov>; Lambertson, David (NIH/NCI) [E] <david.lambertson@nih.gov>; Burke, Andy (NIH/NCI) [E] <andy.burke@nih.gov>
Cc: Berkley, Dale (NIH/OD) [E] <BerkleyD@OD.NIH.GOV>
Subject: IMPORTANT: b5
Importance: High

b5

Thanks,
Mark

Mark L. Rohrbaugh, Ph.D., J.D.
Special Advisor for Technology Transfer
Director, Division of Technology Transfer and Innovation Policy
Office of Science Policy
Office of the Director
National Institutes of Health

From: Berkley, Dale (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5EE461C29F5045A49F0ADF82CAAA2F31-BERKLEYD]
Sent: 8/22/2017 4:12:37 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]
Subject: RE: Comments by KEI on Prospective Grant of Exclusive Patent License: MicroRNA Therapeutics for Treating Squamous Cell Carcinomas to miRecule, Inc.

b5

Best, Dale

Dale D. Berkley, Ph.D., J.D.
Office of the General Counsel, PHD, NIH Branch
Bldg. 31, Rm. 47
Bethesda, MD 20892
301-496-6043
301-402-2528(Fax)
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From: Rohrbaugh, Mark (NIH/OD) [E]
Sent: Monday, August 21, 2017 4:10 PM
To: Berkley, Dale (NIH/OD) [E] <berkleyd@od.nih.gov>
Subject: FW: Comments by KEI on Prospective Grant of Exclusive Patent License: MicroRNA Therapeutics for Treating Squamous Cell Carcinomas to miRecule, Inc.

b5

From: Shmilovich, Michael (NIH/NHLBI) [E]
Sent: Friday, August 18, 2017 12:15 PM
To: Deutch, Alan (NIH/NHLBI) [E] <deutcha@nhlbi.nih.gov>; Reichman, Uri (NIH/NHLBI) [E] <uri.reichman@nih.gov>; Thalhammer-Reyero, Cristina (NIH/NHLBI) [E] <cristina.thalhammer-reyero@nih.gov>; Bailey, Brian (NIH/NHLBI) [E] <bbailey@nhlbi.nih.gov>
Cc: Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>
Subject: FW: Comments by KEI on Prospective Grant of Exclusive Patent License: MicroRNA Therapeutics for Treating Squamous Cell Carcinomas to miRecule, Inc.

Alan, Cristina, Uri, and Brian –
As you probably would have guessed, KEI objected to our notice of intent to grant an exclusive license to miRecule. I'm including a copy of the FR notice, KEI's comments and my draft response seeking your comments.

b5

b5

b5

b5 Happy reading.

Regards,

Michael A. Shmilovich, Esq., CLP
National Heart, Lung, and Blood Institute
Office of Technology Transfer and Development
31 Center Drive Room 4A29, MSC2479
Bethesda, MD 20892-2479
o. 301.435.5019
shmilovm@mail.nih.gov

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From: b6 **On Behalf Of** Jamie Love
Sent: Friday, August 18, 2017 10:17
To: Shmilovich, Michael (NIH/NHLBI) [E] <michael.shmilovich@nih.gov>
Cc: Kim Treanor <kim.treanor@keionline.org>; Diane Singhroy <diane.singhroy@keionline.org>; Andrew S. Goldman <andrew.goldman@keionline.org>; Manon Ress <manon.ress@keionline.org>
Subject: Comments by KEI on Prospective Grant of Exclusive Patent License: MicroRNA Therapeutics for Treating Squamous Cell Carcinomas to miRecule, Inc.

Dear Michael Shmilovich, Esq.

Attached as a PDF file are the Comments by KEI on Prospective Grant of Exclusive Patent License: MicroRNA Therapeutics for Treating Squamous Cell Carcinomas to miRecule, Inc.

Jamie

--
James Love. Knowledge Ecology International
http://www.keionline.org/donate.html
KEI DC tel: +1.202.332.2670, US Mobile: b6 Geneva Mobile: b6 twitter.com/jamie_love

From: Berkley, Dale (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5EE461C29F5045A49F0ADF82CAAA2F31-BERKLEYD]
Sent: 7/9/2018 6:52:07 PM
To: Freel, Rose (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8ae9aab7e3249e881bb573e9a189036-freelrm]; Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]
Subject: RE: KEI letter regarding 83 FR 30448

b5

Dale

From: Freel, Rose (NIH/NCI) [E]
Sent: Monday, July 09, 2018 2:49 PM
To: Berkley, Dale (NIH/OD) [E] <BerkleyD@OD.NIH.GOV>; Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>
Subject: RE: KEI letter regarding 83 FR 30448

Okay, thanks. b5
b5

--
Rose Santangelo Freel, Ph.D.
Technology Transfer Manager
National Cancer Institute
P 301-624-1257 | rose.freel@nih.gov

From: Berkley, Dale (NIH/OD) [E]
Sent: Monday, July 09, 2018 2:42 PM
To: Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>; Freel, Rose (NIH/NCI) [E] <rose.freel@nih.gov>
Subject: RE: KEI letter regarding 83 FR 30448

b5

Let me know if you want to discuss.

Dale D. Berkley, Ph.D., J.D.
Office of the General Counsel, PHD, NIH Branch
Bldg. 31, Rm. 47
Bethesda, MD 20892
301-496-6043
301-402-2528(Fax)
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From: Rohrbaugh, Mark (NIH/OD) [E]
Sent: Monday, July 09, 2018 2:08 PM
To: Freel, Rose (NIH/NCI) [E] <rose.freel@nih.gov>; Berkley, Dale (NIH/OD) [E] <BerkleyD@OD.NIH.GOV>
Subject: RE: KEI letter regarding 83 FR 30448

b5

From: Freel, Rose (NIH/NCI) [E]
Sent: Monday, July 09, 2018 2:01 PM
To: Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>; Berkley, Dale (NIH/OD) [E] <berkleyd@od.nih.gov>
Subject: FW: KEI letter regarding 83 FR 30448

Hi Mark and Dale,

I received the attached letter from KEI this afternoon. Richard is out of the office this week, would you be able to help me b5

Thanks!
Rose

--
Rose Santangelo Freel, Ph.D.
Technology Transfer Manager
National Cancer Institute
P 301-624-1257 | rose.freel@nih.gov

From: Luis Gil Abinader [mailto:luis.gil.abinader@keionline.org]
Sent: Monday, July 09, 2018 1:21 PM
To: Freel, Rose (NIH/NCI) [E] <rose.freel@nih.gov>
Cc: Jamie Love <james.love@keionline.org>; Andrew S. Goldman <andrew.goldman@keionline.org>
Subject: KEI letter regarding 83 FR 30448

Dear Dr. Freel,

Attached please find a letter to you on behalf of Knowledge Ecology International (KEI).

Best regards,

Luis Gil Abinader

From: Jorgenson, Lyric (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/CN=RECIPIENTS/CN=JORGENSONLA]
Sent: 6/8/2017 1:58:44 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=OD/cn=ROHRBAUM]; Wolinetz, Carrie (NIH/OD) [E] [/O=NIH/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=Wolinetzcdc9a]
CC: Plude, Denise (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=Recipients/cn=parksde]; Fennington, Kelly (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=OD/cn=FENNINGTONKNEW]
Subject: FW: WF 365656 - Direct Reply due 6/14
Attachments: 1 CRISPR-SecPrice-6Jan2017.pdf; 2 Email 00381213 7 6 2017.pdf

And now for real…

Mark, can you coordinate with Ann to develop a response? Note that it is a direct reply from OSP, but through Director clearance.

Carrie – b5

From: Plude, Denise (NIH/OD) [E]
Sent: Thursday, June 8, 2017 9:43 AM
To: Jorgenson, Lyric (NIH/OD) [E] <jorgensonla@od.nih.gov>; Fennington, Kelly (NIH/OD) [E] <FenningK@OD.NIH.GOV>
Subject: WF 365656 - Direct Reply due 6/14

Mark?

Work Folder Information
Work Folder: WF 365656
Process: Direct Reply
Program Analyst: Boskent, Celeste (NIH/OD) [E]
Due Date: June 14, 2017
WF Subject: Letter regarding DHHS policy on licensing of CRISPR patents. [Cross Ref: WF 365590]
IC: od_osp
From: Love, JamesGoldman, AndrewSinghroy, Diane
To: Price, Thomas E.
Remarks: OS: Previous FYI. Assigned to OSP for direct reply with Director's clearance. Please upload draft by 6/14/17 (COB). FYI: NHGRI. Thank you.

Letter regarding DHHS policy on licensing of CRISPR patents

From: b6 On Behalf Of Jamie Love

Sent: Monday, June 05, 2017 2:23 PM

To: Collins, Francis (NIH/OD) [E]; Price, Thomas (HHS/OS)

Cc: Andrew S. Goldman; Diane Singhroy; Claire Cassedy; Manon Ress; Thiru Balasubramaniam

Subject: Letter regarding DHHS policy on licensing of CRISPR patents

Dear Secretary Price and NIH Director Francis Collins,

Attached is a letter from KEI asking DHHS to develop a policy on the licensing of CRISPR patents.

James Love

Director

Knowledge Ecology International

--

James Love. Knowledge Ecology International

http://www.keionline.org/donate.html

KEI DC tel: +1.202.332.2670, US Mobile: b6 Geneva Mobile: b6 twitter.com/jamie_love<http://twitter.com/jamie_love>

From: Bruff, Susan (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/CN=RECIPIENTS/CN=BRUFFS]
Sent: 11/7/2016 8:23:25 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=OD/cn=ROHRBAUM]
Subject: RE: Agenda Items

Is KH Kathy Hudson – just confirming.

From: Rohrbaugh, Mark (NIH/OD) [E]
Sent: Monday, November 07, 2016 2:59 PM
To: Bruff, Susan (NIH/OD) [E] <bruffs@od.nih.gov>; OD-OSP Senior Staff <ODODPSS@OD.NIH.GOV>
Subject: RE: Agenda Items

I can provide a quick update on the KH meeting with KEI on Xtandi

From: Bruff, Susan (NIH/OD) [E]
Sent: Monday, November 07, 2016 2:25 PM
To: OD-OSP Senior Staff <ODODPSS@OD.NIH.GOV>
Subject: Agenda Items

All,

Please send me any agenda items that you have for Wednesday's staff meeting by 2:00 PM Tuesday.

Many thanks,
Susan

Susan Bruff
Program Manager
NIH/OD/OSP
6705 Rockledge Drive, Suite 750
Bethesda, Maryland 20892
Phone: 301-594-5419
Fax: 301-496-9839

From: Wolinetz, Carrie (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=1C655040D47346C7B04D7BC11A403ECB-WOLINETZCD]
Sent: 8/16/2017 2:10:45 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]
CC: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]
Subject: Re: PLSRD!

Yes, I think that is fine.

Carrie D. Wolinetz, Ph.D.
Acting Chief of Staff and
Associate Director for Science Policy
Office of the Director
National Institutes of Health
301-496-2122

-------- Original message --------
From: "Rohrbaugh, Mark (NIH/OD) [E]" <rohrbaum@od.nih.gov>
Date: 8/16/17 10:08 AM (GMT-05:00)
To: "Wolinetz, Carrie (NIH/OD) [E]" <carrie.wolinetz@nih.gov>
Cc: "Parker, Ashley (NIH/OD) [E]" <ashley.parker@nih.gov>
Subject: PLSRD!

Sent from my iPhone

On Aug 15, 2017, at 2:24 PM, Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov> wrote:

> Carrie:
>
> b5
>
> Thanks,
> Mark
>
> Mark L. Rohrbaugh, Ph.D., J.D.
> Special Advisor for Technology Transfer
> Director, Division of Technology Transfer and Innovation Policy

Office of Science Policy
Office of the Director
National Institutes of Health

From: Berkley, Dale (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5EE461C29F5045A49F0ADF82CAAA2F31-BERKLEYD]
Sent: 7/15/2019 3:04:10 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]
Subject: RE: Inquiry re: Proposed Exclusive Licenses on CD19 and CD20-related therapies to Kite

Yes I agree.

Dale D. Berkley, Ph.D., J.D.
Office of the General Counsel, PHD, NIH Branch
Bldg. 31, Rm. 47
Bethesda, MD 20892
301-496-6043
301-402-2528(Fax)

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From: Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>
Sent: Monday, July 15, 2019 11:02 AM
To: Berkley, Dale (NIH/OD) [E] <berkleyd@od.nih.gov>
Subject: FW: Inquiry re: Proposed Exclusive Licenses on CD19 and CD20-related therapies to Kite

b5

From: Lambertson, David (NIH/NCI) [E] <david.lambertson@nih.gov>
Sent: Monday, July 15, 2019 10:13 AM
To: Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>
Subject: FW: Inquiry re: Proposed Exclusive Licenses on CD19 and CD20-related therapies to Kite

Good morning Mark,

Richard indicated that I should consult with you regarding how to respond to this inquiry from KEI. Please let me know if there is a general response we should provide to them or if there is some alternative approach you would like to take.

Thanks,
Dave

David A. Lambertson, Ph.D.
Senior Technology Transfer Manager
Technology Transfer Center
National Cancer Institute/NIH
david.lambertson@nih.gov
http://ttc.nci.nih.gov/

9609 Medical Center Drive, Rm 1-E530 MSC 9702
Bethesda, MD 20892-9702 (USPS)
Rockville, MD 20850-9702 (Overnight/express mail)
Phone (Main Office): 240-276-5530
Phone (direct): b6
Fax: 240-276-5504

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From: Claire Cassedy <claire.cassedy@keionline.org>
Sent: Friday, July 12, 2019 2:04 PM
To: Lambertson, David (NIH/NCI) [E] <david.lambertson@nih.gov>
Subject: Inquiry re: Proposed Exclusive Licenses on CD19 and CD20-related therapies to Kite

Dear Dr. Lambertson,

I am writing in reference to the Federal Register notices 84 FR 33272 and 84 FR 33270 regarding,"Prospective Grant of an Exclusive Patent License: Autologus Therapy Using Bicistronic Chimeric Antigen Receptors Targeting CD19 and CD20" and "Prospective Grant of an Exclusive Patent License: Allogeneic Therapy Using Bicistronic Chimeric Antigen Receptors Targeting CD19 and CD20," for which you are listed as the contact for inquiries. I was hoping you could provide me with some further information regarding the status of the technologies.

1. At what stage of development are the inventions listed?
2. Has the government funded any clinical trials relevant to these technologies?
3. If the government has provided funding, how much has been spent by the government on these trials? Can you provide NCT numbers?
4. Is the term in the proposed licenses to be life of patent or less than life of patent?
5. In working towards executing this license, has the NIH sought advice from the Attorney General (as is required under 40 USC § 559) to determine if the "disposal to a private interest would tend to create or maintain a situation inconsistent with antitrust law"?
6. Considering the NIH has previously licensed CAR T technologies to Kite Pharma/Gilead, are the technologies identified in the current Federal Register notice related in any way to the previously executed licenses? (*List of previously noticed exclusive licenses on CAR T technologies to Kite Pharma follows below this email*)
7. Is there a Cooperative Research and Development Agreement associated with this technology?
8. Did the NIH previously post this technology in the Federal Register under "Government Inventions available for licensing"? And/or was it announced on any other platform that these technologies were available for licensing?
9. If not, how was it determined that Kite would enter into this proposed exclusive license, particularly considering the technology is currently under a provisional patent application?
10. Considering Kite/Gilead currently has CAR T therapy Yescarta (axicabtagene ciloleucel) on the market at a price of $373,000, has/will the NIH seek license terms that will ensure the resultant therapy is available to patients on reasonable terms?

Thank you in advance for your assistance in this matter.

Sincerely,

Claire Cassedy

Previously noticed exclusive licenses on CAR T technologies to Kite Pharma:
Prospective Grant of Exclusive License: Development of T Cell Receptors and Chimeric Antigen Receptors Into Therapeutics for Adoptive Transfer in Humans To Treat Cancer
https://www.federalregister.gov/documents/2012/01/24/2012-1383/prospective-grant-of-exclusive-license-development-of-t-cell-receptors-and-chimeric-antigen

Prospective Grant of Exclusive License: Development of T Cell Receptors for Adoptive Transfer in Humans to Treat Cancer
https://www.federalregister.gov/documents/2014/03/25/2014-06412/prospective-grant-of-exclusive-license-development-of-t-cell-receptors-for-adoptive-transfer-in

Prospective Grant of Exclusive License: Development of T Cell Receptors for Adoptive Transfer in Humans To Treat Cancer https://www.federalregister.gov/documents/2014/10/16/2014-24502/prospective-grant-of-exclusive-license-development-of-t-cell-receptors-for-adoptive-transfer-in

Prospective Grant of Exclusive License: The Development of an Anti-CD19 Chimeric Antigen Receptor (CAR) for the Treatment of Human Cancers
https://www.federalregister.gov/documents/2015/06/26/2015-15657/prospective-grant-of-exclusive-license-the-development-of-an-anti-cd19-chimeric-antigen-receptor-car

Prospective Grant of Exclusive Patent License: Development of T Cell Receptors (TCRs) Targeting the KRAS G12D Mutation for the Treatment of Cancer
https://www.federalregister.gov/documents/2016/08/17/2016-19549/prospective-grant-of-exclusive-patent-license-development-of-t-cell-receptors-tcrs-targeting-the

Prospective Grant of Exclusive Patent License: Development of Anti-CD70 Chimeric Antigen Receptors for the Treatment of CD70 Expressing Cancers
https://www.federalregister.gov/documents/2016/10/05/2016-24030/prospective-grant-of-exclusive-patent-license-development-of-anti-cd70-chimeric-antigen-receptors

Prospective Grant of an Exclusive Patent License: The Development of an Anti-CD30 Chimeric Antigen Receptor (CAR) for the Treatment of Human Cancer
https://www.federalregister.gov/documents/2017/12/20/2017-27416/prospective-grant-of-an-exclusive-patent-license-the-development-of-an-anti-cd30-chimeric-antigen

--
Claire Cassedy
Knowledge Ecology International
1621 Connecticut Avenue NW
Suite 500
Washington, DC 20009
Tel.: 1.202.332.2670

From: Frisbie, Suzanne (NIH/NIAID) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=C402740CEAAD4D4F97A8C28F16FBB349-FRISBIES]
Sent: 7/5/2018 3:53:40 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]; Surabian, Karen (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=604a0e2013504631921434a90b327010-surabiank_1]
CC: Mowatt, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb1ef7e2e54b4164ae34814574bda638-mmowatt]; Kirby, Tara (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2368a591fa4c4932a802e5d467fb49ed-tarak]; Sayyid, Fatima (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5b9e45041bdb43719f7113a5aae27057-sayyidf]
Subject: RE: KEI comments on Prospective Grant of Exclusive Patent Commercialization License: Streptococcus Pneumonia PSAA Peptide for Treatment of Sepsis and Infection to The University of Liverpool, located in Liverpool, UK

Thanks Mark, we can leave the response as already drafted previously, b5

From: Rohrbaugh, Mark (NIH/OD) [E]
Sent: Tuesday, July 03, 2018 11:33 AM
To: Frisbie, Suzanne (NIH/NIAID) [E] <suzanne.frisbie@nih.gov>; Surabian, Karen (NIH/NIAID) [E] <karen.surabian@nih.gov>
Cc: Mowatt, Michael (NIH/NIAID) [E] <mmowatt@niaid.nih.gov>; Kirby, Tara (NIH/NIAID) [E] <tara.kirby@nih.gov>; Sayyid, Fatima (NIH/NIAID) [E] <sayyidf@od.nih.gov>
Subject: RE: KEI comments on Prospective Grant of Exclusive Patent Commercialization License: Streptococcus Pneumonia PSAA Peptide for Treatment of Sepsis and Infection to The University of Liverpool, located in Liverpool, UK

Sorry, b5

From: Rohrbaugh, Mark (NIH/OD) [E]
Sent: Tuesday, July 03, 2018 11:31 AM
To: Frisbie, Suzanne (NIH/NIAID) [E] <Suzanne.Frisbie@nih.gov>; Surabian, Karen (NIH/NIAID) [E] <karen.surabian@nih.gov>
Cc: Mowatt, Michael (NIH/NIAID) [E] <MMOWATT@niaid.nih.gov>; Kirby, Tara (NIH/NIAID) [E] <tara.kirby@nih.gov>; Sayyid, Fatima (NIH/NIAID) [E] <SayyidF@OD.NIH.GOV>
Subject: RE: KEI comments on Prospective Grant of Exclusive Patent Commercialization License: Streptococcus Pneumonia PSAA Peptide for Treatment of Sepsis and Infection to The University of Liverpool, located in Liverpool, UK

b5

From: Frisbie, Suzanne (NIH/NIAID) [E]
Sent: Tuesday, July 03, 2018 10:20 AM
To: Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>; Surabian, Karen (NIH/NIAID) [E] <karen.surabian@nih.gov>
Cc: Mowatt, Michael (NIH/NIAID) [E] <mmowatt@niaid.nih.gov>; Kirby, Tara (NIH/NIAID) [E] <tara.kirby@nih.gov>; Sayyid, Fatima (NIH/NIAID) [E] <sayyidf@od.nih.gov>
Subject: RE: KEI comments on Prospective Grant of Exclusive Patent Commercialization License: Streptococcus Pneumonia PSAA Peptide for Treatment of Sepsis and Infection to The University of Liverpool, located in Liverpool, UK

b5

From: Rohrbaugh, Mark (NIH/OD) [E]
Sent: Tuesday, July 03, 2018 10:16 AM
To: Frisbie, Suzanne (NIH/NIAID) [E] <Suzanne.Frisbie@nih.gov>; Surabian, Karen (NIH/NIAID) [E] <karen.surabian@nih.gov>
Cc: Mowatt, Michael (NIH/NIAID) [E] <MMOWATT@niaid.nih.gov>; Kirby, Tara (NIH/NIAID) [E] <tara.kirby@nih.gov>; Sayyid, Fatima (NIH/NIAID) [E] <SayyidF@OD.NIH.GOV>
Subject: RE: KEI comments on Prospective Grant of Exclusive Patent Commercialization License: Streptococcus Pneumonia PSAA Peptide for Treatment of Sepsis and Infection to The University of Liverpool, located in Liverpool, UK

b5

From: Frisbie, Suzanne (NIH/NIAID) [E]
Sent: Tuesday, July 03, 2018 7:58 AM
To: Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>; Surabian, Karen (NIH/NIAID) [E] <karen.surabian@nih.gov>
Cc: Mowatt, Michael (NIH/NIAID) [E] <mmowatt@niaid.nih.gov>; Kirby, Tara (NIH/NIAID) [E] <tara.kirby@nih.gov>; Sayyid, Fatima (NIH/NIAID) [E] <sayyidf@od.nih.gov>
Subject: RE: KEI comments on Prospective Grant of Exclusive Patent Commercialization License: Streptococcus Pneumonia PSAA Peptide for Treatment of Sepsis and Infection to The University of Liverpool, located in Liverpool, UK

I agree with Mark's comments. b5
b5

From: Rohrbaugh, Mark (NIH/OD) [E]
Sent: Monday, July 02, 2018 3:12 PM
To: Surabian, Karen (NIH/NIAID) [E] <karen.surabian@nih.gov>
Cc: Frisbie, Suzanne (NIH/NIAID) [E] <Suzanne.Frisbie@nih.gov>; Mowatt, Michael (NIH/NIAID) [E] <MMOWATT@niaid.nih.gov>; Kirby, Tara (NIH/NIAID) [E] <tara.kirby@nih.gov>; Sayyid, Fatima (NIH/NIAID) [E] <SayyidF@OD.NIH.GOV>
Subject: RE: KEI comments on Prospective Grant of Exclusive Patent Commercialization License: Streptococcus Pneumonia PSAA Peptide for Treatment of Sepsis and Infection to The University of Liverpool, located in Liverpool, UK

I am getting so many of these, please remind me if I have this correct. b5

b5

From: Surabian, Karen (NIH/NIAID) [E]
Sent: Monday, July 02, 2018 3:05 PM
To: Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>
Cc: Frisbie, Suzanne (NIH/NIAID) [E] <Suzanne.Frisbie@nih.gov>; Mowatt, Michael (NIH/NIAID) [E] <MMOWATT@niaid.nih.gov>; Kirby, Tara (NIH/NIAID) [E] <tara.kirby@nih.gov>; Sayyid, Fatima (NIH/NIAID) [E] <SayyidF@OD.NIH.GOV>
Subject: FW: KEI comments on Prospective Grant of Exclusive Patent Commercialization License: Streptococcus Pneumonia PSAA Peptide for Treatment of Sepsis and Infection to The University of Liverpool, located in Liverpool, UK

Hello Mark,

Does the following email and attached from KEI b5
b5

Thank you.

Sincerely,

Karen

Karen T. Surabian
Licensing and Patenting Manager
CDC Team
Technology Transfer and Intellectual Property Office (TTIPO)
National Institute of Allergy and Infectious Diseases (NIAID)
National Institutes of Health (NIH)
5601 Fishers Lane, Rm. 2G48, MSC 9804
Rockville, MD 20892

Phone: +1-301-594-9719
Email: karen.surabian@nih.gov

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From: James Love <james.love@keionline.org>
Sent: Monday, July 2, 2018 2:52 PM
To: Surabian, Karen (NIH/NIAID) [E] <karen.surabian@nih.gov>
Cc: Luis Gil Abinader <luis.gil.abinader@keionline.org>; Claire Cassedy <claire.cassedy@keionline.org>
Subject: KEI comments on Prospective Grant of Exclusive Patent Commercialization License: Streptococcus Pneumonia PSAA Peptide for Treatment of Sepsis and Infection to The University of Liverpool, located in Liverpool, UK

--
James Love. Knowledge Ecology International
http://www.keionline.org/donate.html
KEI DC tel: +1.202.332.2670, US Mobile: b6 Geneva Mobile: b6 twitter.com/jamie_love

From: Thalhammer-Reyero, Cristina (NIH/NHLBI) [E] [/O=NIH/OU=NIHEXCHANGE/CN=OD/CN=THALHAMC]
Sent: 1/9/2017 8:30:43 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=OD/cn=ROHRBAUM]
CC: Deutch, Alan (NIH/NHLBI) [E] [/O=NIH/OU=NIHEXCHANGE/cn=NHLBIOS/cn=DeutchA]
Subject: RE: ACTION - Example response to KEI FR notice
Attachments: image001.jpg

Thank you Mark. I am receiving also others from NCI following your request.

Best regards,
Cristina

From: Rohrbaugh, Mark (NIH/OD) [E]
Sent: Monday, January 09, 2017 3:17 PM
To: Thalhammer-Reyero, Cristina (NIH/NHLBI) [E]
Cc: Deutch, Alan (NIH/NHLBI) [E]
Subject: FW: ACTION - Example response to KEI FR notice

Here is one from NIAID

From: Soukas, Peter (NIH/NIAID) [E]
Sent: Monday, January 09, 2017 3:09 PM
To: Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>
Cc: Frisbie, Suzanne (NIH/NIAID) [E] <frisbies@otd.nci.nih.gov>; Mowatt, Michael (NIH/NIAID) [E] <MMOWATT@niaid.nih.gov>; Williams, Richard (NIH/NIAID) [E] <RWILLIAMS@niaid.nih.gov>; Puglielli, Maryann (NIH/NIAID) [E] <maryann.puglielli@nih.gov>
Subject: RE: ACTION - Example response to KEI FR notice

Dear Mark,

As requested, attached please find NIH/NIAID's response to KEI's comments from a 2016 FR publication. We believe NCI has also provided multiple responses to Jamie Love and suggest that you contact Richard Rodriguez as well. Thanks.

Peter Soukas
National Institutes of Health
National Institute of Allergy and Infectious Diseases
Technology Transfer and Intellectual Property Office
Suite 6D
5601 Fishers Lane, MSC9804
Rockville, MD 20852-9804
Phone: 301-594-8730
Fax: 240-627-3117
Email: ps193c@nih.gov<mailto:ps193c@nih.gov>
http://www.niaid.nih.gov/LabsAndResources/techDev/Pages/default.aspx

From: Mowatt, Michael (NIH/NIAID) [E]
Sent: Monday, January 09, 2017 2:58 PM
To: Soukas, Peter (NIH/NIAID) [E] <peter.soukas@nih.gov<mailto:peter.soukas@nih.gov>>; Williams, Richard (NIH/NIAID) [E] <RWILLIAMS@niaid.nih.gov<mailto:RWILLIAMS@niaid.nih.gov>>; Puglielli, Maryann (NIH/NIAID) [E] <maryann.puglielli@nih.gov<mailto:maryann.puglielli@nih.gov>>
Cc: Frisbie, Suzanne (NIH/NIAID) [E] <frisbies@otd.nci.nih.gov<mailto:frisbies@otd.nci.nih.gov>>; Mowatt, Michael (NIH/NIAID) [E] <MMOWATT@niaid.nih.gov<mailto:MMOWATT@niaid.nih.gov>>
Subject: ACTION - Example response to KEI FR notice

All,

Mark Rohrbaugh is looking for an example of a response to KEI objection to a FR notice intent to grant an exclusive license.

As I recall we did one for the Sanofi RSV license.

If my memory serves me correctly, please send to Mark. If not, please let me know.

Thanks,

Mike
Michael R. Mowatt, Ph.D.
Director, Technology Transfer and Intellectual Property Office

National Institute of Allergy and Infectious Diseases

National Institutes of Health
U.S. Department of Health and Human Services

+1 301 496 2644

[NIH_NIAID_Master_Logo_2Color]

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National Institute of
Allergy and
Infectious Diseases

From: Rohrbaugh, Mark (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=591AB6B2424B4B8997082718CBB29FAB-ROHRBAUM]
Sent: 12/7/2017 3:59:51 PM
To: NIH TDC Long [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1266a38ae3aa4208baa3753f5054395f-NIH TDC Lon]; OD-OTT [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=601fac9463b64189b4069135db2d336d-OD-OTT]
Subject: FW: KEI Op-ed in the Hill urging HHS nominee Azar to march in to control drug prices

http://thehill.com/opinion/healthcare/363322-american-taxpayers-will-be-alex-azars-shareholders-lets-hope-he-can-serve

"Laws exist which are intended to protect the public's investment. After an initial discovery is made, the federal agency, university, or biotech firm which owns the patent may decide to license it to a larger manufacturer who will be responsible for clinical development and bringing the drug to market.

When the research which led to this patent was publicly funded, however, the law stipulates that the licensee is responsible for making the "benefits of the invention", or the drug created, "available to the public on reasonable terms."

In practice, HHS has consistently failed to enforce this rule. The result is not only that United States citizens pay the highest prices in the world for medicines, but that they're going bankrupt to pay for medicines they technically already own."

From: Hammersla, Ann (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/CN=RECIPIENTS/CN=HAMMERSLAA]
Sent: 5/4/2016 6:11:38 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=OD/cn=ROHRBAUM]
Subject: FW: [Due Wed. 05/11] Necessary Action #346104
Attachments: 346104.zip; Draft Response to Dr Fulton 05042016 ah.docx; Summary of Biolyse and Slavitt's request 05042016.docx

Mark:

Attached is my summary of the requestor Fulton and my recommendation that b5 b5

Let me know what your edits are. I would like to finalize this, if at all possible, before tomorrow afternoon before I b6

Ann

From: Fern, Gizem (NIH/OD) [C]
Sent: Thursday, April 28, 2016 3:38 PM
To: Hammersla, Ann (NIH/OD) [E] <hammerslaa@mail.nih.gov>
Cc: Bulls, Michelle G. (NIH/OD) [E] <michelle.bulls@nih.gov>; Helfer, Jacqueline (NIH/OD) [C] <jacqueline.helfer@nih.gov>
Subject: [Due Wed. 05/11] Necessary Action #346104

Hello Ms. Ann Hammersla,

Received from Exec Sec – Attn: Ann Hammersla. Please work with OSP to prepare a draft Direct Reply that should be provided to Exec Sec for clearance by **Wednesday, May 11**.

- Encloses letter from Bridget Kiecken, President, Biolyse Pharma, to Andy Slavitt, Acting Administrator for CMS, offering to supply Medicare and programs with generic versions of enzalutamide (Xtandi), which treats prostate cancer. Also is interested in approaching the NIH to use its march-in rights in patents for the drug to supply affordable versions of the drug to developing countries, including South Africa.

Please provide the draft response to me by **Wednesday, May 11** for clearance before sending the response.

Thank you for your time,

Gizem Fern
Executive Assistant | Deputy Director of the Office of Extramural Research
Master Key Consulting-Contractor
National Institutes of Health
One Center Drive
Bldg. 1, Rm. 144
Bethesda, MD 20892
MWF ☎: 301-594-5123
📠: 301-402-3469

Rockledge 1 - 5040A
TTh ☎: 301-402-3740

✉: gizem.fern@nih.gov

From: John R. Fulton [invent@bion.ca]
Sent: 4/24/2016 2:27:47 AM
To: Slavitt, Andy (CMS/OA) [/O=NIH/OU=NIHEXCHANGE/cn=Recipients/cn=Andy.Slavitt.CMS]
CC: Collins, Francis (NIH/OD) [E] [/O=NIH/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=Collinsfr]; Jamie Love [james.love@keionline.org]
Subject: See attached: offer to supply low cost enzalutamide
Attachments: Biolyse Pharma letter.pdf

Andy Slavitt
Acting Administrator for the Centers for Medicare & Medicaid Services (CMS)
Via Email: Andy.Slavitt@cms.hhs.gov

Francis Collins, M.D., Ph.D.
Director
National Institutes of Health
9000 Rockville Pike
Bethesda, MD 20892
Via: Francis.Collins@nih.hhs.gov

Dear Administrator Slavitt and Director Collins,

I am a private biotechnology consultant representing Biolyse Pharma Corporation in St.Catharines Ontario. I have attached a letter from Bridgitte Kiecken, the President of Biolyse Pharma, offering to supply Medicare and programs with generic versions of enzalutamide, a drug to treat prostate cancer, at $3 per 40 mg tablet. In 2014, Medicare was paying $69.41 per tablet for Xtandi, the Astellas version of the drug, so the Biolyse offer involves dramatic savings to the U.S. government.

The federal government has a royalty free right to use the following three patents on this product: 7709517, 8183274 and 9123941. The Biolyse offer is contingent upon the federal government using the royalty free right to obtain less expensive supplies of the drug.

Separately, Biolyse Pharma would be interested in approaching the NIH to use its rights in the patents to supply affordable versions of enzalutamide in developing countries, including South Africa.

I would be interested in talking with your staff about this offer,

Sincerely,

John R. Fulton
BioNiagara
5 Garden Park Blvd.
St.Catharines, Ontario
Canada
L2R-5B8
905.932.7883
Biolyse@Biolyse.com

Corporation
Biolyse Pharma
Corporation

59 Welland Vale Rd., St. Catharines
Ontario Canada L2S 3Y2
Tel: (905) 687-8008
Fax: (905) 687-4923
Toll Free: 1-877-234-1880
E-mail: biolyse@sympatico.ca

Andy Slavitt
Acting Administrator for the Centers for Medicare & Medical Services (CMS)

April, 22nd, 2016

Dear Mr. Slavitt,

Biolyse Pharma is a Canadian company that specializes in the manufacturing as well as the development of sterile oncology drugs.

We are presently writing to express our willingness to supply a generic version of enzalutamide to prostate cancer patients in the United States and in the developing world.

Presently enzalutamide is sold under the name Xtandi by Astella Pharmaceuticals. It is our understanding, that in 2014, prostate cancer patients receiving reimbursement for their medication were paying an excess of $250 dollars for their daily regime of four tablets of 40mg of enzalutamide. Astella is presently selling in Canada and in other jurisdictions Xtandi for approximately 30% of what it is presently charging in the United States. Biolyse Pharma would be able to supply enzalutamide for approximately $3.00 USD per tablet.

Medicare has a royalty free right in all three patents in the FDA orange book for enzalutamide. We believe we can have generic versions approved by the FDA in less than three years if CMS is willing to allow Biolyse Pharma to supply the drug using the U.S federal government's worldwide royalty free license.

Sincerely,

Brigitte Kiecken
President

Corporation Biolyse Pharmacopee Internationale

Biolyse Pharmacopoeia International Corporation

From: Collins, Francis (NIH/OD) [E] [/O=NIH/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=COLLINSFR]
Sent: 4/24/2016 9:06:36 AM
To: Wolinetz, Carrie (NIH/OD) [E] [/O=NIH/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=Wolinetzcdc9a]
CC: Hudson, Kathy (NIH/OD) [E] [/O=NIH/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=Hudsonkl]; Tabak, Lawrence (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=nidcr/cn=tabakl]
Subject: FW: See attached: offer to supply low cost enzalutamide
Attachments: Biolyse Pharma letter.pdf

Now here's a new twist....

From: John R. Fulton [mailto:invent@bion.ca]
Sent: Saturday, April 23, 2016 10:28 PM
To: Slavitt, Andy (CMS/OA)
Cc: Collins, Francis (NIH/OD) [E]; Jamie Love
Subject: See attached: offer to supply low cost enzalutamide

Andy Slavitt
Acting Administrator for the Centers for Medicare & Medicaid Services (CMS)
Via Email: Andy.Slavitt@cms.hhs.gov

Francis Collins, M.D., Ph.D.
Director
National Institutes of Health
9000 Rockville Pike
Bethesda, MD 20892
Via: Francis.Collins@nih.hhs.gov

Dear Administrator Slavitt and Director Collins,

I am a private biotechnology consultant representing Biolyse Pharma Corporation in St.Catharines Ontario. I have attached a letter from Bridgitte Kiecken, the President of Biolyse Pharma, offering to supply Medicare and programs with generic versions of enzalutamide, a drug to treat prostate cancer, at $3 per 40 mg tablet. In 2014, Medicare was paying $69.41 per tablet for Xtandi, the Astellas version of the drug, so the Biolyse offer involves dramatic savings to the U.S. government.

The federal government has a royalty free right to use the following three patents on this product: 7709517, 8183274 and 9123941. The Biolyse offer is contingent upon the federal government using the royalty free right to obtain less expensive supplies of the drug.

Separately, Biolyse Pharma would be interested in approaching the NIH to use its rights in the patents to supply affordable versions of enzalutamide in developing countries, including South Africa.

I would be interested in talking with your staff about this offer,

Sincerely,

John R. Fulton
BioNiagara
5 Garden Park Blvd.
St.Catharines, Ontario
Canada
L2R-5B8
905.932.7883
Biolyse@Biolyse.com

Draft Response to Dr. Collins:

John R. Fulton
BioNiagara
5 Garden Park Blvd.
St. Catherines, Ontario
Canada

Email: John R. Fulton: invent@bion.ca

Dear Dr. Fulton:

b5

Sincerely,

05/04/2016 DEITR to OSP

Exec Sec Draft Response: 346104; response Due 05/11/2016;

b5

From: Soukas, Peter (NIH/NIAID) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B1F6020157AC47948C6E34166B78E433-SOUKASP]
Sent: 1/31/2019 8:16:06 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]; Berkley, Dale (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5ee461c29f5045a49f0adf82caaa2f31-berkleyd]; Mowatt, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb1ef7e2e54b4164ae34814574bda638-mmowatt]; Frisbie, Suzanne (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c402740ceaad4d4f97a8c28f16fbb349-frisbies]; Williams, Richard (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e5f89fe4d27a43abb936bb20efeca3b9-rwilliams]; Puglielli, Maryann (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9f53ceacaf754875a948081bac5cc66a-pugliellim]
Subject: RE: KEI Response Letter
Attachments: Response to KEI J Love Comments NIAID Final MLR 01 31 2019.docx

Dear Mark,

Thanks for the revisions, the letter looks better. Attached please find a clean, non-redlined version.

b5

If you approve, I will ask Mike Mowatt et al. to approve the letter as well, then send it to Jamie Love. Thank you.

Peter Soukas
National Institutes of Health
National Institute of Allergy and Infectious Diseases
Phone: 301-594-8730
Email: ps193c@nih.gov

From: Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>
Sent: Wednesday, January 30, 2019 4:40 PM
To: Soukas, Peter (NIH/NIAID) [E] <peter.soukas@nih.gov>; Berkley, Dale (NIH/OD) [E] <berkleyd@od.nih.gov>; Mowatt, Michael (NIH/NIAID) [E] <mmowatt@niaid.nih.gov>; Frisbie, Suzanne (NIH/NIAID) [E] <suzanne.frisbie@nih.gov>; Williams, Richard (NIH/NIAID) [E] <rwilliams@niaid.nih.gov>; Puglielli, Maryann (NIH/NIAID) [E] <maryann.puglielli@nih.gov>
Subject: RE: KEI Response Letter

Looks good Peter. I made a few small suggestions and ask a question for clarification. Thx

From: Soukas, Peter (NIH/NIAID) [E] <peter.soukas@nih.gov>
Sent: Wednesday, January 30, 2019 3:54 PM
To: Berkley, Dale (NIH/OD) [E] <berkleyd@od.nih.gov>; Mowatt, Michael (NIH/NIAID) [E] <mmowatt@niaid.nih.gov>; Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>; Frisbie, Suzanne (NIH/NIAID) [E] <suzanne.frisbie@nih.gov>; Williams, Richard (NIH/NIAID) [E] <rwilliams@niaid.nih.gov>; Puglielli, Maryann (NIH/NIAID) [E] <maryann.puglielli@nih.gov>
Subject: Re: KEI Response Letter

Dear Dale and Mark,

We hope everything is going well with you. Thank you for the productive conversation last week.

Attached please find a further draft letter for your review and/or approval.

Please contact us if you have any additional questions. Thank you once again for your help.

Peter Soukas
Phone: 301-594-8730
Email: ps193c@nih.gov

From: Berkley, Dale (NIH/OD) [E]
Sent: Wednesday, January 23, 2019 12:51 PM
To: Mowatt, Michael (NIH/NIAID) [E]; Rohrbaugh, Mark (NIH/OD) [E]; Frisbie, Suzanne (NIH/NIAID) [E]; Soukas, Peter (NIH/NIAID) [E]; Williams, Richard (NIH/NIAID) [E]; Puglielli, Maryann (NIH/NIAID) [E]
Subject: RE: KEI Response Letter

Attached is a proposed draft for the call at 1pm

Dale D. Berkley, Ph.D., J.D.
Office of the General Counsel, PHD, NIH Branch
Bldg. 31, Rm. 47
Bethesda, MD 20892
301-496-6043
301-402-2528(Fax)
This message is intended for the exclusive use of the recipient(s) named above. It may contain information that is PROTECTED or PRIVILEGED, and it should not be disseminated, distributed, or copied to persons not authorized to receive such information.

-----Original Message-----
From: Mowatt, Michael (NIH/NIAID) [E] <mmowatt@niaid.nih.gov>
Sent: Tuesday, January 22, 2019 12:53 PM
To: Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>; Frisbie, Suzanne (NIH/NIAID) [E] <suzanne.frisbie@nih.gov>; Soukas, Peter (NIH/NIAID) [E] <peter.soukas@nih.gov>; Williams, Richard (NIH/NIAID) [E] <rwilliams@niaid.nih.gov>; Puglielli, Maryann (NIH/NIAID) [E] <maryann.puglielli@nih.gov>
Cc: Berkley, Dale (NIH/OD) [E] <berkleyd@od.nih.gov>; Mowatt, Michael (NIH/NIAID) [E] <mmowatt@niaid.nih.gov>
Subject: RE: KEI Response Letter

Team,

I ran into Dale just now at NIH. He generously offered to draft a response and will circulate it prior to our call tomorrow. We shouldn't need more than 15 or 30 minutes tomorrow.

Thanks Dale and everyone,

Mike

-----Original Message-----
From: Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>
Sent: Tuesday, January 22, 2019 12:24 PM
To: Mowatt, Michael (NIH/NIAID) [E] <mmowatt@niaid.nih.gov>
Cc: Frisbie, Suzanne (NIH/NIAID) [E] <suzanne.frisbie@nih.gov>; Soukas, Peter (NIH/NIAID) [E] <peter.soukas@nih.gov>; Williams, Richard (NIH/NIAID) [E] <rwilliams@niaid.nih.gov>; Puglielli, Maryann (NIH/NIAID) [E] <maryann.puglielli@nih.gov>; Berkley, Dale (NIH/OD) [E] <berkleyd@od.nih.gov>
Subject: Re: KEI Response Letter

Just saw this. Do you have time now?

Sent from my iPhone

> On Jan 22, 2019, at 11:59 AM, Mowatt, Michael (NIH/NIAID) [E] <mmowatt@niaid.nih.gov> wrote:
>
> b5
> Leader - b5
> Participant - b5
>
>
> Thanks, Mary.
>
> This one is a priority, so please squeeze it in this week. Tomorrow afternoon?
>
>
>
>
> Dear Mary,
>
> We are just following up, we hope everything is going well with you.
>
> Does Mike have any time this week to discuss these issues with Mark Rohrbaugh and Dale Berkley?
>
> We look forward to a meeting invitation soon.
>
> Thank you.
>
> Peter
> <meeting.ics>

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health/ NIAID

5601 Fishers Lane
Rockville, MD 20852
Suite 6D, MSC 9804
Tel (301) 496-2644

February 1, 2019

James Love
Director
Knowledge Ecology International
1621 Connecticut Ave., Suite 500
Washington, DC 20009
+1.202.332.2670
james.love@keionline.org

Subject: Comments Submitted in Response to Federal Register Notice 2018-65696 (83 FR 65696), entitled "Prospective Grant of Exclusive Patent License: Production of Live Respiratory Syncytial Virus and Parainfluenza Virus Vaccines"

Dear Mr. Love:

b5

b5

b5

Sincerely,

Technology Transfer and Patent Specialist

From: Fine, Amanda (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=61290B74AA9A44358954C45439FFDEB6-FINEAB]
Sent: 4/26/2019 4:03:46 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]
CC: Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]; Wojtowicz, Emma (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=45c6610aca6e44a08d497630425e5ecd-wojtowiczem]
Subject: RE: Media Inquiry: CRS report and march-in petitions

Hi Mark-

We wouldn't comment on petitions under review, correct?

Thanks,
Amanda

From: Fine, Amanda (NIH/OD) [E]
Sent: Friday, April 26, 2019 11:57 AM
To: Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>
Cc: Myles, Renate (NIH/OD) [E] <mylesr@mail.nih.gov>; Wojtowicz, Emma (NIH/OD) [E] <emma.wojtowicz@nih.gov>
Subject: RE: Media Inquiry: CRS report and march-in petitions

Ok thanks Mark, much appreciated!

Amanda

From: Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>
Sent: Friday, April 26, 2019 11:56 AM
To: Fine, Amanda (NIH/OD) [E] <amanda.fine@nih.gov>
Cc: Myles, Renate (NIH/OD) [E] <mylesr@mail.nih.gov>; Wojtowicz, Emma (NIH/OD) [E] <emma.wojtowicz@nih.gov>
Subject: RE: Media Inquiry: CRS report and march-in petitions

The 6 on the website are the ones where we completed a review and closed out the case. In terms of the requests themselves, they are probably on the KEI website. I don't what they mean by the other 6. I will check.

From: Fine, Amanda (NIH/OD) [E] <amanda.fine@nih.gov>
Sent: Friday, April 26, 2019 11:52 AM
To: Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>
Cc: Myles, Renate (NIH/OD) [E] <mylesr@mail.nih.gov>; Wojtowicz, Emma (NIH/OD) [E] <emma.wojtowicz@nih.gov>
Subject: Media Inquiry: CRS report and march-in petitions

Hi Mark-

Please see the highlighted sections of the below request. To summarize, this reporter is asking to about the petitions NIH has received to exercise march-in rights. She asking to see the petitions, and NIH responses. She also is asking if NIH has comment on a report from Department of Commerce National Institute of Standards and Technology that proposed to prevent the use of march-in rights based on the price of a product. We were not sure if we would even comment on a draft report—but wanted to check with you about how best to respond this inquiry.

If you're not the right person, would you be able to recommend who we should ask in OTT?

Thanks,
Amanda

From: Sandburg, Brenda <Brenda.Sandburg@informa.com>
Sent: Wednesday, April 24, 2019 11:59 AM
To: Fine, Amanda (NIH/OD) [E] <amanda.fine@nih.gov>
Subject: RE: reporter's query re: CRS report and march-in petitions

Hi Amanda,

The NIST final draft Green Paper came out this morning. It mentions that NIH has received 12 requests to initiate march-in proceedings. Six of them are on your website. Could you provide the full list of 12?
I am particularly interested in NIH's views on the report. The questions about the CRS report on NIH can wait.

Many thanks,
Brenda

Information Classification: General

From: Fine, Amanda (NIH/OD) [E] <amanda.fine@nih.gov>
Sent: Tuesday, April 23, 2019 5:54 PM
To: Sandburg, Brenda <Brenda.Sandburg@informa.com>
Cc: Myles, Renate (NIH/OD) [E] <mylesr@mail.nih.gov>; Wojtowicz, Emma (NIH/OD) [E] <emma.wojtowicz@nih.gov>
Subject: RE: reporter's query re: CRS report and march-in petitions

Hi Brenda-

Thanks for your email. We'll look into your request and get back to you.

Best,
Amanda

Amanda Fine
Deputy, News Media Branch
National Institutes of Health
Tel: 301-496-7246
Email: amanda.fine@nih.gov
Web: http://www.nih.gov

NIH . . . *Turning Discovery Into Health*

From: Sandburg, Brenda <Brenda.Sandburg@informa.com>
Sent: Tuesday, April 23, 2019 3:55 PM
To: Fine, Amanda (NIH/OD) [E] <amanda.fine@nih.gov>; Wojtowicz, Emma (NIH/OD) [E] <emma.wojtowicz@nih.gov>
Subject: reporter's query re: CRS report and march-in petitions

Hi Amanda and Emma,

I would like to get your input on two different subjects.

First, does NIH have a list of “march-in” petitions asking NIH to exercise its right to license patents derived from federally funded research?
NIH’s responses to petitions are on your website https://www.ott.nih.gov/policy/policies-reports - and I wondered if this is a complete list of petitions submitted to NIH.
Also, what does NIH think about the forthcoming final draft report by the Department of Commerce’s National Institute of Standards and Technology proposing to prevent the use of march-in rights based on the price of a product?

The second topic is the Congressional Research Service’s report on NIH that was issued April 19, which gives a broad overview of NIH regarding the budget, funding and research priorities.
Do you know how CRS came to write this report? Did NIH have input on it?
Does NIH have any comments about CRS’ conclusions?
Particularly, does NIH have a view regarding congressional directives to focus on specific areas of research, including Alzheimer’s disease? The report says that some in the scientific community worry that attention on Alzheimer’s may detract from research on other diseases.

Many thanks,
Brenda

Brenda Sandburg
Senior Editor
The Pink Sheet
Informa
605 3rd Ave.
New York, NY 10158
212-520-2730
brenda.sandburg@informa.com

Information Classification: General

From: Myles, Renate (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7D317F5626934585B3692A1823C1B522-MYLESR]
Sent: 6/21/2018 8:10:22 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]
Subject: RE: quick question from a journalist
Attachments: Ed Silverman Response.docx

See suggested changes. If you're okay with this, perhaps you can loop me in with David and I'll loop the NCI press office in to handle the response to Ed.

From: Rohrbaugh, Mark (NIH/OD) [E]
Sent: Thursday, June 21, 2018 4:00 PM
To: Myles, Renate (NIH/OD) [E] <mylesr@mail.nih.gov>
Subject: RE: quick question from a journalist

b5

From: Myles, Renate (NIH/OD) [E]
Sent: Thursday, June 21, 2018 3:33 PM
To: Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>
Subject: RE: quick question from a journalist

b5

From: Rohrbaugh, Mark (NIH/OD) [E]
Sent: Thursday, June 21, 2018 3:32 PM
To: Myles, Renate (NIH/OD) [E] <mylesr@mail.nih.gov>
Subject: RE: quick question from a journalist

b5

From: Myles, Renate (NIH/OD) [E]
Sent: Thursday, June 21, 2018 3:25 PM
To: Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>
Subject: RE: quick question from a journalist

b5

b5

From: Rohrbaugh, Mark (NIH/OD) [E]
Sent: Thursday, June 21, 2018 3:08 PM
To: Myles, Renate (NIH/OD) [E] <mylesr@mail.nih.gov>
Subject: FW: quick question from a journalist

b5

From: Lambertson, David (NIH/NCI) [E]
Sent: Thursday, June 21, 2018 3:05 PM
To: Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>
Cc: Rodriguez, Richard (NIH/NCI) [E] <richard.rodriguez@nih.gov>
Subject: FW: quick question from a journalist

Hi Mark,

I also received this question from a non-KEI entity. b5

Thanks,

David A. Lambertson, Ph.D.
Senior Technology Transfer Manager
Technology Transfer Center
National Cancer Institute/NIH
david.lambertson@nih.gov
http://ttc.nci.nih.gov/

9609 Medical Center Drive, Rm 1-E530 MSC 9702
Bethesda, MD 20892-9702 (USPS)
Rockville, MD 20850-9702 (Overnight/express mail)
Phone (Main Office): 240-276-5530
Phone (direct): b6
Fax: 240-276-5504

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From: Silverman, Ed [mailto:ed.silverman@statnews.com]
Sent: Thursday, June 21, 2018 11:25 AM
To: Lambertson, David (NIH/NCI) [E] <david.lambertson@nih.gov>
Subject: quick question from a journalist

Hi Dave,

My name is Ed Silverman and I run the Pharmalot blog at The Boston Globe's STAT health news site, where I track the pharmaceutical industry.

A quick question about the NIH notice to provide a license to Beoro Therapeutics for a cancer drug...

https://www.federalregister.gov/documents/2018/06/07/2018-12179/prospective-grant-of-an-exclusive-patent-license-the-development-of-an-anti-bcma-immunotoxin-for-the

There's not a lot of publicly available information about Beoro and wondering why the agency chose this company. What info exists to give taxpayers confidence that such a license would be awarded to a company with the expertise and capabilities to develop the technology?

It seems one of the Beoro folks - Gerhard Niederfellner - worked at Roche. Can you confirm this and provide some insight into how this company was chosen?

Thanks
ed silverman
STAT / Pharmalot
973-493-7851
www.statnews.com/pharmalot/

b5

From: Lambert, Richard (NIH/NIAID) [C] [/O=NIH/OU=NIHEXCHANGE/CN=NIAID/CN=LAMBERTR]
Sent: 6/1/2017 11:08:07 AM
To: Mowatt, Michael (NIH/NIAID) [E] [/O=NIH/OU=NIHEXCHANGE/cn=NIAID/cn=MMOWATT]; Rohrbaugh, Mark (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=OD/cn=ROHRBAUM]; Berkley, Dale (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=OD/cn=BERKLEYD]
Subject: FW: [Ip-health] Fred Abbott in IP-Watch: US Supreme Court Adopts International Exhaustion For Patents: Paving the way for parallel imports to exert downward pressure on domestic pharmaceutical (and other) prices

Jamie Love's take on Lexmark

Richard A. Lambert
Contractor
National Institute of Allergy and Infectious Diseases
National Institutes of Health
U.S. Department of Health and Human Services
5601 Fishers Lane, Rm. 2G47, MSC 9804
Bethesda, MD 20892-9804
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301.496.2644 main officeline
240.627.3706 direct line
FAX 240.627.3117
lambertr@niaid.nih.gov
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-----Original Message-----
From: Jamie Love [mailto:james.love@keionline.org]
Sent: Wednesday, May 31, 2017 6:21 PM
To: Ip-health <ip-health@lists.keionline.org>
Subject: [Ip-health] Fred Abbott in IP-Watch: US Supreme Court Adopts International Exhaustion For Patents: Paving the way for parallel imports to exert downward pressure on domestic pharmaceutical (and other) prices

https://www.ip-watch.org/2017/05/31/us-supreme-court-adopts-international-exhaustion-patents-paving-way-parallel-imports-exert-downward-pressure-domestic-pharmaceutical-prices/

US Supreme Court Adopts International Exhaustion For Patents: Paving the way for parallel imports to exert downward pressure on domestic pharmaceutical (and other) prices
31/05/2017

By Frederick M Abbott*

The Supreme Court of the United States on May 30, 2017 adopted a rule of international exhaustion of patent rights for the United States in Impression Products v. Lexmark International, No. 15-1189. The near-unanimous decision authored by Chief Justice Roberts is unambiguous and unequivocal.[1] The Court paid short shrift to contrary decisions of the Court of Appeals for the Federal Circuit in Jazz Photo Corp. v.
International Trade Commission, 264 F. 3d 1094 (Fed. Cir. 2001) and in this case on certiorari, Lexmark International v. Impression Products, 816 F.3d
721 (Fed. Cir. 2016).

In addition to adopting international exhaustion, the Supreme Court ruled firmly against enforcement of post-sale restrictions through infringement actions based on patent. The Court allowed for enforcement under contract law of limitations that may be included in patent licenses.

Only Justice Ginsberg dissented, and only as to the international exhaustion issue. (Justice Gorsuch did not take part.) It is noteworthy that the decision by Chief Justice Roberts is written in "plain English" without efforts to mystify the judgment, or to keep its meaning obscure to the non-lawyer.

The Supreme Court decision applies across the subject matter spectrum with respect to patents in the United States, and affects all industry sectors.
Computer and electronics equipment manufacturers, major retailers and others expressed their views in amicus briefs. The issue of international exhaustion of patents and parallel importation is of particular interest for the pharmaceutical sector. Advocates of parallel importation — this author included — have pointed to the pro-competitive effects inherent in cross-border trade in pharmaceutical products once patent rights have been exhausted.[2] Pharmaceutical originators have argued that anything that decreases

their profits hurts R&D, a position which taken to its logical conclusion justifies unlimited price increases.

The United States has the highest originator pharmaceutical prices in the world and contributes the largest share of originator industry revenues.
The US public stands to gain from the downward pricing pressure that may come from parallel imports of patented pharmaceuticals. The beneficial effects should not be overestimated. There are constraints on the potential available supply of parallel import products that will moderate the impact within the US market, but almost any downward pricing pressure will be a step in the right direction.

In the decision on appeal, the Federal Circuit's main argument against international exhaustion was that a US patent owner should be entitled to a first sale in the United States so that it can secure a US territorial price that is likely to be higher than a foreign price for the same product. The Federal Circuit viewed this as a patent entitlement flowing from its (mistaken) understanding of independence of patents and corresponding territorial limitations.

In rejecting the Federal Circuit's reasoning, the Supreme Court said that the principal issue under US law is whether the patent owner has authorized a sale; either in the United States or abroad. The Court said that US exhaustion doctrine makes no geographical distinction regarding the place of sale. The Court noted that it was deciding against the backdrop of long-standing common-law doctrine disfavoring restraints on alienation. It said that the US Congress was aware of the common-law environment in which it legislates, and that Congress chose not to adopt a rule limiting exhaustion of patents to first sales in the United States.

The Court rejected a suggestion to distinguish its holding in Kirtsaeng v.
Wiley, 133 S Ct. 1351 (2013) in favor of international exhaustion for copyright. The Court observed that products marketed in the United States may contain thousands of patents, and that its concerns about downstream restrictions on foreign sales are as serious in respect to patents as they are in respect to copyrights.

The Supreme Court distinguished Boesch v. Graff, 133 U.S. 697 (1890), the decision the Federal Circuit had improvidently relied on in Jazz Photo, on grounds that the German first seller in Boesch was not the US patentee, but rather an independent German firm. The US patent owner had not authorized the first sale abroad, and had not exhausted its right to sue an importer for infringement.

The Supreme Court decision does not specifically address itself to pharmaceuticals, though the decision applies across patent subject matter, and thus to pharmaceuticals. The Federal Circuit addressed the pharmaceutical sector in its decision (and in oral argument before the en banc Federal Circuit), and the Supreme Court was doubtless aware of the sectoral implications.

Members of Congress introduced legislation to authorize importation of prescription medicines in advance of the Supreme Court decision. They avoided addressing the patent question, preferring to let the Supreme Court speak first. The Supreme Court has now cleared away potential patent obstacles to parallel importation of medicines first sold outside the United States. Further US legislation may not be required before parallel importers begin bringing patented medicines into the United States if such medicines are produced in FDA-inspected and approved facilities abroad, the medicines have been approved for sale in the United States and chain of custody records are satisfactory. Other circumstances may (or may not) require additional legislation. The FDA may in any case propose additional measures directed toward regulating parallel importers.

The originator industry will not sit idly by as its pricing power is diminished. If past is prologue, every argument against parallel imports that can be made will be made, and more. Quite a few members of Congress have promised to take steps to reduce pharmaceutical prices. We will see whether these promises can withstand the traditional pharmaceutical industry lobbying pressure. On a more upbeat note, members of Congress might realize they can use the decision of the Supreme Court for "cover".
With the Supreme Court favoring price competition to constrain patent monopolists, perhaps this will not be such a stretch for the Congress.

* Edward Ball Eminent Scholar Prof. of International Law, Florida State University College of Law, USA.

[1] Although further vindication was hardly necessary following adoption by WTO Members of the Doha Declaration on the TRIPS Agreement and Public Health, the decision of the US Supreme Court affirms the position taken by the government of South Africa in its defense of international exhaustion of patents in the Medicines and Related Substances Control Amendment Act of 1997.

[2] This author filed an amicus brief with the Supreme Court addressing issues surrounding pharmaceutical patents, and supporting international exhaustion. PhRMA, BIO and other pharmaceutical industry groups filed amicus briefs to contrary effect

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James Love. Knowledge Ecology International http://www.keionline.org/donate.html
KEI DC tel: +1.202.332.2670, US Mobile: b6 Geneva Mobile:
b6 twitter.com/jamie_love

Ip-health mailing list

Ip-health@lists.keionline.org
http://lists.keionline.org/mailman/listinfo/ip-health_lists.keionline.org

From: Soukas, Peter (NIH/NIAID) [E] [/O=NIH/OU=NIHEXCHANGE/CN=OD/CN=SOUKASP]
Sent: 1/9/2017 8:09:16 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=OD/cn=ROHRBAUM]
CC: Frisbie, Suzanne (NIH/NIAID) [E] [/O=NIH/OU=Nihexchange/cn=nci/cn=frisbies]; Mowatt, Michael (NIH/NIAID) [E] [/O=NIH/OU=NIHEXCHANGE/cn=NIAID/cn=MMOWATT]; Williams, Richard (NIH/NIAID) [E] [/O=NIH/OU=NIHEXCHANGE/cn=NIAID/cn=RWILLIAMS]; Puglielli, Maryann (NIH/NIAID) [E] [/O=NIH/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=Pugliellim]
Subject: RE: ACTION - Example response to KEI FR notice
Attachments: Untitled Attachment

Dear Mark,

As requested, attached please find NIH/NIAID's response to KEI's comments from a 2016 FR publication. We believe NCI has also provided multiple responses to Jamie Love and suggest that you contact Richard Rodriguez as well. Thanks.

Peter Soukas
National Institutes of Health
National Institute of Allergy and Infectious Diseases
Technology Transfer and Intellectual Property Office
Suite 6D
5601 Fishers Lane, MSC9804
Rockville, MD 20852-9804
Phone: 301-594-8730
Fax: 240-627-3117
Email: ps193c@nih.gov
http://www.niaid.nih.gov/LabsAndResources/techDev/Pages/default.aspx

---

From: Mowatt, Michael (NIH/NIAID) [E]
Sent: Monday, January 09, 2017 2:58 PM
To: Soukas, Peter (NIH/NIAID) [E] <peter.soukas@nih.gov>; Williams, Richard (NIH/NIAID) [E] <RWILLIAMS@niaid.nih.gov>; Puglielli, Maryann (NIH/NIAID) [E] <maryann.puglielli@nih.gov>
Cc: Frisbie, Suzanne (NIH/NIAID) [E] <frisbies@otd.nci.nih.gov>; Mowatt, Michael (NIH/NIAID) [E] <MMOWATT@niaid.nih.gov>
Subject: ACTION - Example response to KEI FR notice

All,

Mark Rohrbaugh is looking for an example of a response to KEI objection to a FR notice intent to grant an exclusive license.

As I recall we did one for the Sanofi RSV license.

If my memory serves me correctly, please send to Mark. If not, please let me know.

Thanks,

Mike
Michael R. Mowatt, Ph.D.
Director, Technology Transfer and Intellectual Property Office

National Institute of Allergy and Infectious Diseases
National Institutes of Health
U.S. Department of Health and Human Services

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National Institute of
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Infectious Diseases

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From: Soukas, Peter (NIH/NIAID) [E] [/O=NIH/OU=NIHEXCHANGE/CN=OD/CN=SOUKASP]
Sent: 3/22/2016 8:33:02 PM
To: 'Jamie Love' [james.love@keionline.org]

Dear Mr. Love,

We write to confirm receipt of your comments (dated March 8, March 4, and February 22, 2016) regarding the Federal Register Notice at F.R. Vol. 82, No. 34 (page 8728), published on Monday, February 22, 2016. NIH considers all written comments received in response to notices. When making a final determination to grant an exclusive patent license, NIH complies with the statutes and regulations for licensing inventions, including 37 C.F.R. section 404.7, and determines that the public will be served by the granting of the license, that an exclusive or partially exclusive license is reasonable and necessary, and that the proposed scope of exclusivity is not greater than reasonably necessary.

Peter Soukas
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Email: ps193c@nih.gov
http://www.niaid.nih.gov/LabsAndResources/techDev/Pages/default.aspx

From: Burke, Andy (NIH/NCI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=305E280EDC664E68939D4348603F56E6-BURKEAR]
Sent: 7/10/2019 8:15:40 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]; Rodriguez, Richard (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8092cb5394e04733ac0d4d84d25f65e5-rodrigr]
Subject: Draft Response to KEI FR Comments
Attachments: Tailored Therapeutics, cell therapies license, 2 July 2019 KEI comments.pdf; Response to KEI K Ardizzone Comments_draft 7-10-19.docx

Hi Mark and Richard,

Please find attached KEI's objection/comments to my recent FR notice, along with my draft response to the same. Let me know if you have any concerns.

Thank you,

Andy

Andrew R. Burke, Ph.D.
Senior Technology Transfer Manager
National Cancer Institute
9609 Medical Center Drive, Rm 1E550
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July 2, 2019

Andrew Burke, Ph.D.
Senior Technology Transfer Manager
NCI Technology Transfer Center
9609 Medical Center Drive, RM 1E530, MSC 9702
Bethesda, MD 20892-9702

Via email: andy.burke@nih.gov

Re: 84 FR 28063, Prospective Grant of an Exclusive Patent License: Development and Commercialization of Cell Therapies for Cancer, to Tailored Therapeutics, LLC ("Tailored"), located in Potomac, MD.

Dear Dr. Burke:

Knowledge Ecology International (KEI) and the Union for Affordable Cancer Treatment (UACT) are writing to provide comments on the prospective grant of an exclusive patent license for the development and commercialization of cell therapies for cancer, to Tailored Therapeutics, LLC. ("Tailored"), located in Potomac, MD.

On June 24, 2019, Claire Cassedy from KEI emailed you five questions about the proposed license. You replied with answers to her questions on June 24, 2019. On June 26, 2019, Luis Gil Abinader from KEI emailed you eight additional questions about the proposed license. You replied with answers to his questions on June 27, 2019. Thank you again for your replies. Claire Cassedy also emailed you on June 24, 2019 regarding whether the NIH has sought advice from the Attorney General as is required under 40 U.S.C. § 559, we have yet to receive a reply to that inquiry. We are providing a copy of these emails, including your replies, attached with our comments.

The NIH should comply with 40 U.S.C. § 559, which is not preempted by the Bayh-Dole Act.

At the appropriate time in the licensing process, we expect the NIH to obtain advice from the Attorney General (as is required under 40 U.S.C. § 559) to determine if the "disposal to a private interest would tend to create or maintain a situation inconsistent with antitrust law."

40 U.S.C. § 559 is not preempted by the Bayh-Dole Act, which provides that "[n]othing in this chapter shall be deemed to convey to any person immunity from civil or criminal liability, or to create any defenses to actions, under any antitrust law[.]" 35 U.S.C. § 211.

The Bayh-Dole Act sets out the areas where the statute "shall take precedence over any other Act which would require a disposition of rights in subject inventions[,]" 35 U.S.C § 210, and mentions 21 separate statutes, but does not include 40 U.S.C. § 559.

Intellectual property

The Federal Register notice divides the intellectual property covered in the proposed license into two groups: Group A and Group B. Group A includes two U.S. provisional patent applications. Group B includes one U.S. provisional patent application and a PCT procedure.

	NIH Reference Number	**Type**	**Number**	**Filing Date**	**Title**
Group A	E-166-2018-0-US-01	Provisional	62/749,750	October 24, 2018	HLA-A3-RESTRICTED T CELL RECEPTORS AGAINST MUTATED RAS
	E-029-2019-0-US-01	Provisional	62/795,203	January 22, 2019	HLA CLASS II-RESTRICTED T CELL RECEPTORS AGAINST RAS WITH G12R MUTATION
Group B	E-094-2018-0-US-01	Provisional	62/661,941	April 24, 2018	METHODS OF PRODUCING T CELL POPULATIONS USING HYDROXYCITRIC ACID AND/OR A SALT THEREOF
	E-094-2018-0-PCT-02	PCT	PCT/US2019/028513	April 22, 2019	METHODS OF PRODUCING T CELL POPULATIONS USING HYDROXYCITRIC ACID AND/OR A SALT THEREOF

We searched the three U.S. provisional patent applications using the USPTO Public Patent Application Information Retrieval (PAIR) system and the Patent Application Full Text and Image Database (AppFT). This search returned zero results. We note that these provisional applications were filed in April 2018, October 2018, and January 2019, and the USPTO normally does not publish these types of applications for 18 months, pursuant to 35 U.S.C. § 122.

We also searched the PCT application PCT/US2019/028513 using the WIPO PatentScope database, and obtained zero results. We infer from the Federal Register notice that the earliest priority of the PCT procedure was the U.S. provisional application 62/661,941, filed April 2018. Article 21 of the Patent Cooperation Treaty provides that, subject to exceptions, "the international publication of the international application shall be effected promptly after the expiration of 18 months from the priority date of that application."[1] If the priority was indeed filed on April 2018, the application PCT/US2019/028513 may not be published for several more months.

Our search suggests that none of the patent documents listed in the Federal Register notice have been published. In your June 27, 2019 email you confirmed that none of these applications have been published. In order to have a clear understanding of the intellectual property that will be covered in the license we have to be able to read the patent claims. Patent documents often contain additional useful information, such as the name of the inventors involved. Not being able to scrutinize those documents prior to the deadline established in the Federal Register notice undermines our ability to understand and comment on whether the proposed license is "a reasonable and necessary incentive" as provided under 35 U.S.C. § 209.

According to the Federal Register notice the territory of the proposed license "may be worldwide." The PCT application was filed in April 2019, which means that it is still well within the deadline to start the national phase in PCT member countries, including several developing countries. The Federal Register notice failed to explain in which countries the NIH intends to start the national phase, despite the fact that this is information necessary to understand and comment on whether the proposed license is "a reasonable and necessary incentive" as provided under 35 U.S.C. § 209. Nevertheless, we will assume that the geographical scope of the license could include several developing countries via the PCT procedure.

Field of use

The proposed license divides the field of use in two: one that applies to Groups A and B, and one that applies to Group B. The field of use that applies to Groups A and B is the following:

> "Development, manufacture and commercialization of autologous, peripheral blood T cell therapy products engineered by CRISPR to express T cell receptors reactive to mutated KRAS, as claimed in the Licensed Patent Rights, for the treatment of human cancers. Specifically excluded from this field of use are retrovirally-engineered peripheral blood T cell therapy products for the treatment of human cancers.
>
> Development, manufacture and commercialization of companion diagnostics approved or cleared by the FDA or equivalent foreign regulatory agency for Licensee-proprietary T cell therapy products."

---

[1] https://www.wipo.int/pct/en/texts/articles/a21.html#_21

The field of use that applies to Group B is the following:

> “Development, manufacture and commercialization of autologous, peripheral blood T cell therapy products engineered by CRISPR to express T cell receptors reactive to mutated p53, as claimed in the Licensed Patent Rights, for the treatment of cancer in humans.
>
> “Development, manufacture and commercialization of autologous, tumor infiltrating lymphocyte (TIL)-based adoptive T cell therapy products reactive to mutated p53, isolated as claimed in the Licensed Patent Rights, for the treatment of human cancers. Specifically excluded from this field of use are genetically engineered TIL cell therapy products for the treatment of human cancers.
>
> Development, manufacture and commercialization of companion diagnostics approved or cleared by the FDA or equivalent foreign regulatory agency for Licensee-proprietary T cell therapy products.”

The Federal Register notice further explains the following about Group A:

> “Intellectual Property Group A is primarily directed to isolated T cell receptors (TCRs) reactive to mutated Kirsten rat sarcoma viral oncogene homolog (KRAS), within the context of several human leukocyte antigens (HLAs). Mutated KRAS, which plays a well-defined driver role in oncogenesis, is expressed by a variety of human cancers, including: pancreatic, lung, endometrial, ovarian and prostate. Due to its restricted expression in precancerous and cancerous cells, this antigen may be targeted on mutant KRAS-expressing tumors with minimal normal tissue toxicity.”

The Federal Register notice provides the following information about Group B:

> “Intellectual Property Group B is primarily directed to methods of preparing isolated populations of T cells by culturing them in the presence of hydroxycitric acid and/or a salt thereof, and methods of treating cancer using populations of T cells cultured in such a manner.”

KEI sought the advice of a scientist and attorney with extensive expertise in intellectual property in the field of life sciences, who provided us with the following comment:

> “The Field is fairly limited to CRISPR-facilitated T cell modification; it excludes the kind of technology found in CART therapies (good and bad; limited license that encourages a competitive alternative to CART, but not competition within CART). It's also limited to specific T cell receptor sequences to KRAS oncoprotein targets, and to targeting p53 oncoproteins by chemically modifying T cells. Without looking at the patent claims it's hard to guess what they are hoping for; what they will get is likely to be narrower. So it

> could be an important license but from this first pass not an unduly broad or anti-competitive one."

On June 24, 2019, Claire Cassedy from KEI asked you the following questions via email:

> 1. At what stage of development are the inventions listed?
>
> 2. Has the government funded any clinical trials relevant to these technologies?
>
> 3. If the government has provided funding, how much has been spent by the government on these trials? Can you provide NCT numbers?
>
> 4. How many years of exclusivity have been offered in this agreement, and what will the royalty rate be?
>
> 5. Regarding the company to receive the licenses, Tailored Therapeutics, LLC are any former NIH employees associated with the company?

On June 24, 2019, you emailed a reply with answers to each question. An excerpt of your email is reproduced below and a full copy is attached to these comments.

> 1. At what stage of development are the inventions listed?
> Answer: With respect to the advertised fields of use, the technologies are at a "pre-clinical" stage of development.
>
> 2. Has the government funded any clinical trials relevant to these technologies?
> Answer: I am not aware of any US government-funded clinical trials utilizing the referenced technologies within the advertised fields of use.
>
> 3. If the government has provided funding, how much has been spent by the government on these trials? Can you provide NCT numbers?
> Answer: NA
>
> 4. How many years of exclusivity have been offered in this agreement, and what will the royalty rate be?
> Answer: These terms will be the subject of negotiation and are not known at this time.
>
> 5. Regarding the company to receive the licenses, Tailored Therapeutics, LLC are any former NIH employees associated with the company?
> Answer: Questions regarding employees or associates of the company should be directed to the company.

Tailored Therapeutics, LLC

According to the Maryland Business Entity Search website, Tailored Therapeutics was registered on June 5, 2018.[2] Tailored Therapeutics describes itself as “a development stage biotechnology company working on a new way of treating cancer – cell therapy – that uses the patient’s own immune cells to attack the tumor.”[3] According to its website, Tailored Therapeutics has four product candidates, all of which are in preclinical stage: TCEL-100, TCEL-200, and TT-400 for solid tumors; and TT-300 for pancreatic, colorectal, and lung.

The previous license to Tailored Therapeutics, LLC

On September 28, 2018, the NIH published the Federal Register notice 83 FR 49109, which also described a prospective exclusive license to Tailored Therapeutics (hereinafter the “2018 exclusive license”).[4] We asked you whether the 2018 exclusive license and the current license concerned the same company, and you replied in the affirmative in your June 27, 2019 email. We also asked you whether the 2018 exclusive license had been executed, and you replied in the affirmative in your June 27, 2019 email. Although we note that the NIH could have mentioned in the Federal Register notice that the proposed license intended to amend an existing license, describe the existing license, and explain the extent of the proposed amendment, we appreciate your June 27, 2019 email in response to our questions.

Our questions on the 2018 exclusive license and your June 27, 2019 reply are copied below.

> “Is the prospective licensee mentioned in the Federal Register notice 84 FR 28063, Tailored Therapeutics, the same company that appeared as prospective licensee in the Federal Register notice 83 FR 49109, published on September 28, 2018?”
>
> “Answer: Yes, both FR notices concern the same company.”
>
> “Was the license proposed in the Federal Register notice 83 FR 49109 executed?”
>
> “Answer: Yes, the license was executed.”
>
> “Will the exclusive license proposed in the Federal Register notice 84 FR 28063 amend the previous license described in the Federal Register notice 83 FR 49109? In which ways and to what extent?”
>
> “Answer: If the proposed license described in 84 FR 28063 is executed, it will be as an amendment to the company’s existing license. Should this occur, the existing license would be amended to include the patent rights listed in 84 FR 28063 in the fields of use described in the same.”

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[2] https://egov.maryland.gov/BusinessExpress/EntitySearch/BusinessInformation/W18873646

[3] https://tailored-therapeutics.com/

[4] https://www.federalregister.gov/d/2018-21096

> “If this is the case, what is the rationale for granting additional exclusive rights to a company that presumably has outstanding obligations under a previous license?”
>
> “Answer: The company requested a broader scope to their existing license and provided an adequate commercial development plan describing how it will bring the referenced patent rights to practical application within the fields of use described.”

The 2018 exclusive license included 36 patent documents divided into three groups: Groups A, B, and C. The 36 applications were filed in Australia, Canada, China, the European Patent Office, Hong Kong, Israel, Japan, Korea, Mexico, New Zealand, Saudi Arabia, Singapore, the United States, and included three international PCT applications.

The 2018 exclusive license described its intellectual property groups A, B, and C as follows:

> “Intellectual Property Group A is primarily directed to isolated T cell receptors (TCRs) reactive to mutated Kirsten rat sarcoma viral oncogene homolog (KRAS), within the context of several human leukocyte antigens (HLAs). Mutated KRAS, which plays a well-defined driver role in oncogenesis, is expressed by a variety of human cancers, including: Pancreatic, lung, endometrial, ovarian and prostate. Due to its restricted expression in precancerous and cancerous cells, this antigen may be targeted on mutant KRAS-expressing tumors with minimal normal tissue toxicity.”
>
> “Intellectual Property Group B is primarily directed to isolated TCRs reactive to mutated tumor protein 53 (TP53 or P53), within the context of several HLAs. P53 is the archetypal tumor suppressor gene and the most frequently mutated gene in cancer. Contemporary estimates suggest that >50% of all tumors carry mutations in P53. Because of its prevalence in cancer and its restricted expression to precancerous and cancerous cells, this antigen may be targeted on mutant P53-expressing tumors with minimal normal tissue toxicity.”
>
> “Intellectual Property Group C is primarily directed to methods of isolating T cells which are reactive to mutated P53 antigens. Briefly, pools of 25-mer peptides covering known P53 “hotspot” mutations have been generated. These peptides may be pulsed into autologous antigen presenting cells which are subsequently co-cultured with the patient's isolated T cells. Reactive T cells may be purified and expanded in vitro to generate an autologous cell therapy product. The expanded cells may be administered to the patient and mediate tumor regression.”

With regards to the field of use there appear to be some coincidences in both Federal Register notices. For example, both notices have the following paragraph in their field of use sections:

> “Development, manufacture and commercialization of autologous, peripheral blood T cell therapy products engineered by CRISPR to express T cell receptors reactive to mutated KRAS, as claimed in the Licensed Patent Rights, for the treatment of human cancers. Specifically excluded from this field of use are retrovirally-engineered peripheral blood T cell therapy products for the treatment of human cancers.”

The Ziopharm Oncology exclusive license

On February 7, 2019, the NIH published the Federal Register notice 84 FR 2537, describing a prospective exclusive license to Ziopharm Oncology, Inc. KEI, Public Citizen, Social Security Works, and UACT filed comments to the NIH on this license, which are available here: https://www.keionline.org/29777

Although the prospective licensee in that case is a different company, there is a least one patent document, 62/749,750, that is listed in the Federal Register notice 84 FR 2537 as well as the current Federal Register notice, 84 FR 28063. In your June 27, 2019 reply to our email you explained that you were not aware of a relationship between Tailored Therapeutics and Ziopharm Oncology. It is unclear whether Ziopharm Oncology and Tailored Therapeutics have any business relationship, or share any of their stockholders, nor whether these proposed licenses include safeguards against potential anti-competitive behaviors that these two companies may engage in during the exploitation of the underlying exclusive rights.

In the event that the NIH decides to grant this exclusive license, we ask that the following safeguards be placed on the license.

1. **Price discrimination.** Any cell therapy or other medical technology using the patented invention should be available in the United States at a price that does not exceed the median price in the seven largest economies by GDP that have at least 50 percent of the GNI per capita as the United States, using the World Bank Atlas method. This is a modest safeguard.

2. **Low and middle income countries.** The exclusive license should not extend to countries with a per capita income less than 30 percent of the United States, in order to ensure that the patents do not lead to restricted and unequal access in developing countries. If the NIH rejects this suggestion, it needs to provide something that will give effect to the policy objective in the “United States Public Health Service Technology Transfer Policy Manual, Chapter No. 300, PHS Licensing Policy,” which states the following: “PHS seeks to promote commercial development of inventions in a way that provides broad accessibility for developing countries.”

3. **Global registration and affordability.** The license should require Tailored Therapeutics to disclose the steps it will take to enable the timely registration and availability of the cell

therapy or other medical technology at an affordable price in the United States and in every country with a demonstrated need, according to the Centers for Disease Control and Prevention (CDC) and/or the World Health Organization (WHO), either by supplying a country directly at an affordable, publicly disclosed price and with sufficient quantities, or by providing technology transfer and rights to all intellectual property necessary for third parties to do so.

4. **Medicines Patent Pool.** The NIH should retain a right to grant the WHO, the Medicines Patent Pool or other governments the rights to use the patent rights to procure the cell therapy or other medical technology from competitive suppliers, including technology transfer, in developing countries, upon a finding by HHS or the WHO that people in these markets do not have sufficient access to the cell therapy or other medical technology.

5. **Years of exclusivity.** We propose the license reduce the years of exclusivity when revenues are large. The NIH has many options, including by providing an option for non-exclusive licensing, such as was done in the ddI case. We propose that the exclusivity of the license be reduced when the global cumulative sales from products or services using the inventions exceed certain benchmarks. For example, the period of exclusivity in the license could be reduced by one year for every $500 million in global cumulative revenue after the first $1 billion in global sales.This request is consistent with the statutory requirements of 35 U.S.C § 209, which requires that “the proposed scope of exclusivity is not greater than reasonably necessary to provide the incentive for bringing the invention to practical application.”

6. **Transparency of R&D outlays.** The licensee should be required to file an annual report to the NIH, available to the public, on the research and development (R&D) costs associated with the development of any product or service that uses the inventions, including reporting separately and individually the outlays on each clinical trial. We will note that this is not a request to see a company business plan or license application. We are asking that going forward the company be required to report on actual R&D outlays to develop the subject inventions. Reporting on actual R&D outlays is important for determining if the NIH is meeting the requirements of 35 U.S.C. § 209, that “the proposed scope of exclusivity is not greater than reasonably necessary to provide the incentive for bringing the invention to practical application.” Specifically, having data on actual R&D outlays on each clinical trial used to obtain FDA approval provides evidence that is highly relevant to estimating the risk-adjusted costs of bringing NIH licensed inventions to practical application.

Sincerely,

Kathryn Ardizzsone and Luis Gil Abinader, on behalf of:

Knowledge Ecology International (KEI)
Union for Affordable Cancer Treatment (UACT)

And in their personal capacity,

James Love
Manon Ress
Luis Gil Abinader

DEPARTMENT OF HEALTH & HUMAN SERVICES

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July 10, 2019

Kathryn Ardizzone, Esq.
Knowledge Ecology International
1621 Connecticut Avenue, Suite 500
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+1.202.332.2670
james.love@keionline.org

Subject: Comments Submitted in Response to Federal Register Notice 2019-12707 (84 FR 28063), entitled "Prospective Grant of an Exclusive Patent License: Development and Commercialization of Cell Therapies for Cancer"

Dear Ms. Ardizzone:

b5

Sincerely,

Andrew Burke, Ph.D.
Senior Technology Transfer Manager

From: Andrew S. Goldman [andrew.goldman@keionline.org]
Sent: 11/7/2016 6:45:01 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=OD/cn=ROHRBAUM]
Subject: June letter re: march-in / Xtandi

Hi Mark,

My apologies, I looked again at the June letter for the first time in a while and you are right -- it did mention the royalty-free right. Our primary criticism of the letter was that our petition centered around issues of price, but the response dodges that question and instead focuses on the fact that we did not specify a current of future shortage of supply.

Thank you again for your time today.

Best,
Andy

--
Andrew S. Goldman
Counsel, Policy and Legal Affairs
Knowledge Ecology International
andrew.goldman@keionline.org // www.twitter.com/ASG_KEI
tel.: +1.202.332.2670
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From: Berkley, Dale (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5EE461C29F5045A49F0ADF82CAAA2F31-BERKLEYD]
Sent: 7/3/2018 1:55:27 PM
To: Lambertson, David (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3c95b34f709746a8a2553ce54e74ace2-lambertsond]; Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]
CC: Rodriguez, Richard (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8092cb5394e04733ac0d4d84d25f65e5-rodrigr]
Subject: RE: Draft KEI Response

Dave—can you send me their objection?

Thanks, Dale

Dale D. Berkley, Ph.D., J.D.
Office of the General Counsel, PHD, NIH Branch
Bldg. 31, Rm. 47
Bethesda, MD 20892
301-496-6043
301-402-2528(Fax)
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From: Lambertson, David (NIH/NCI) [E]
Sent: Monday, July 02, 2018 4:04 PM
To: Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>; Berkley, Dale (NIH/OD) [E] <BerkleyD@OD.NIH.GOV>
Cc: Rodriguez, Richard (NIH/NCI) [E] <richard.rodriguez@nih.gov>
Subject: Draft KEI Response

Good afternoon Mark and Dale,

I attach a draft response to KEI, who has objected to a recent Notice of Intent to Grant an exclusive license, for your review and consideration. Please let me know if you think the response is acceptable or if you would suggest changes before the response is sent. If you need anything else, let me know.

Thanks,
Dave

David A. Lambertson, Ph.D.
Senior Technology Transfer Manager
Technology Transfer Center
National Cancer Institute/NIH
david.lambertson@nih.gov
http://ttc.nci.nih.gov/

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From: Nightingale, Stuart (NIH/OD) [C] [/O=NIH/OU=NIHEXCHANGE/CN=RECIPIENTS/CN=NIGHTINS]
Sent: 6/8/2016 11:55:11 AM
To: Rohrbaugh, Mark (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=OD/cn=ROHRBAUM]; Dodson, Sara (NIH/OD) [E] [/O=NIH/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=Dodsonse]
Subject: Fwd: Nature Medicine | News | Opinion: Use the Bayh-Dole Act to lower drug prices for government healthcare programs

FYI--
Stuart

Sent from my iPhone

Begin forwarded message:

> **From:** "Folkers, Greg (NIH/NIAID) [E]" <GFOLKERS@niaid.nih.gov>
> **Date:** June 7, 2016 at 11:24:32 PM EDT
> **Subject: Nature Medicine | News | Opinion: Use the Bayh-Dole Act to lower drug prices for government healthcare programs**
>
> Nature Medicine | News | Opinion
>
> -
>
> # Use the Bayh-Dole Act to lower drug prices for government healthcare programs
>
> - Alfred B Engelberg
> - & Aaron S Kesselheim
>
> Published online
> 07 June 2016
>
> As drug prices have increased, there is also greater pressure to find ways to ensure access to medicines. An existing provision of the Bayh-Dole Act could help to lower costs for qualifying drugs in federal programs such as Medicare and Medicaid.
>
> The Bayh-Dole Act of 1980 permits the ownership of patents resulting from federally-funded research to remain with the inventors and their employers. Government research grantees and their institutions now earn billions from royalties and equity interests that result from the sale or exclusive licensing of these patents.[1] In recent years, controversy has arisen when drugs covered by these patents have been sold at excessively high prices, since taxpayers have already contributed to the drugs' discovery, as part of the more than $30 billion annually the US government spends on biomedical research.
>
> In discussing ways to reduce drug costs, legislators and public-health advocates have largely overlooked a provision in the Bayh-Dole Act that could help. Section 202 requires research grantees that obtain patents claiming federally funded inventions to confer a nonexclusive, royalty-free license back to the US government, which permits the government to practice the invention or to have it practiced on the government's behalf. When advocating for the enactment

of the Bayh-Dole Act, former Senator Birch Bayh (D-IN) stated that this license allows the government to "use for itself and the public good inventions arising out of research that the Federal Government helps to support."[2] This use could include that for government healthcare programs such as Medicare and Medicaid.

To our knowledge, the government has never exercised its right to have a prescription drug manufactured on its behalf. One reason may be that, although many drugs have their origins in federally funded research, pharmaceutical companies obtain other patents covering these drugs during their development into FDA-approved products. The government's license does not extend to such privately funded patents, which limits the situations in which the government could use its license.

Still, Section 202 could be useful in some cases. Earlier this year, two consumer-interest organizations, Knowledge Ecology International and Union for Affordable Cancer Treatment, filed a petition requesting the government to use Section 202 to authorize the production of a generic version of the prostate cancer drug enzalutamide (Xtandi), because the drug's list price in the US is two to three times higher than it is in Europe and Australia. All patents currently registered with the US Food and Drug Administration (FDA) covering enzalutamide are licensed to the US government under Section 202. As this article went to press, the US Department of Health and Human Services had not yet ruled on the petition. But the government has received an offer from a generic manufacturer to supply enzalutamide for government programs at $3 per pill, as compared to the $42.38 per pill the government now pays—a potential annual savings of over $57,000 per patient.

A potential obstacle to the exercise of the government's Section 202 license is the patent certification requirements of the Hatch-Waxman Act of 1984. Hatch-Waxman requires a manufacturer that is seeking approval to sell a generic copy of a new drug such as enzalutamide to certify that any patents on the drug are invalid or will not be infringed. This requirement may seem to prevent a generic manufacturer that has no basis for substantively challenging enzalutamide's patents from obtaining FDA approval before the patents expire. But because of the government's Section 202 license, we believe that a generic manufacturer could certify that the patents will not be infringed because approval is being sought for the sole purpose of producing enzalutamide for sale to the government.

Any suit claiming infringement of the enzalutamide patents despite such a certification should be dismissed by a federal court, because the law[3] prohibits the court from interfering with the right of a government supplier to bid on or participate in the sale of products to the government, irrespective of the existence of patents.[4] The only available course of action for acts of patent infringement by or for the government is to initiate a suit in the US Court of Federal Claims—but the Section 202 license would provide the government with a complete defense. In addition to its patents, enzalutamide is protected under Hatch-Waxman by a five-year exclusivity for new chemical entities that expires on 31 August 2017, but an application for generic approval containing a certification of noninfringement may be filed 1 year before the exclusivity expires. There are other drugs, such as the anti-HIV medication emtricitabine (Emtriva), subject to a Section 202 license for which a similar patent certification could be filed immediately.

Some will argue that by exercising its license, the government would undermine the value of commercial rights and adversely affect the willingness of the pharmaceutical industry to invest in the commercialization of federally funded research discoveries. But many manufacturers have reduced their investment in internal drug discovery research and become increasingly dependent on licensing ideas emerging from public funding. There is no reason to believe that they will abandon their essential relationship with academia simply because profits are reduced somewhat by the operation of the Section 202 license.

“The economic benefits that result from federally funded biomedical research should be more equitably shared with the public.”

The economic benefits that result from federally funded biomedical research should be more equitably shared with the public, and the section 202 license can help accomplish that goal for certain drugs. In the long run, Congress should consider ways to amend the Bayh-Dole Act to achieve this outcome more broadly. Until then, the government should utilize its Section 202 license to achieve lower drug prices for public programs whenever possible.

References

- References•
- Author information

1. Watanabe, T. UCLA will get hundreds of millions for rights to prostate cancer drug. LA Times (4 March 2016).
    - Show context
2. http://bayhdolecentral.com/JoeAllen_part3/statment.on.s.414.pdf.
    - Show context
3. 28 U.S.C. § 1498(a) (2015).
    - Show context
4. Gore v. Garlock, 842 F.2d 1275, 1282 (Fed. Cir. 1988).
    - Show context

Download references

Author information

- References•
- Author information

Affiliations

1. <!--[if !supportLists]--><!--[endif]-->**Alfred B. Engelberg is a trustee at the Engelberg Foundation in Palm Beach, Florida, and**
2. <!--[if !supportLists]--><!--[endif]-->**Aaron S. Kesselheim is an associate professor of medicine at the Brigham and Women's Hospital and Harvard Medical School in Boston.**

From: Koniges, Ursula (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=D5AE2C3139654BC0B9B95718D516310B-KONIGESUM]
Sent: 1/31/2019 7:17:05 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]
CC: Plank-Bazinet, Jennifer (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0a7faf0b33bb4b90b07b212e49ec08e3-plankjl_f24]; Fennington, Kelly (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3e2d306aa244429b0f51d365bd24a26-fenningk]
Subject: RE: Drug Pricing BRAIN Record – Ursula Has Uploaded Into BRAIN

Hi Mark, thanks for this. I'll update the sentence to the following for clarity:

b5

From: Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>
Sent: Thursday, January 31, 2019 2:15 PM
To: Koniges, Ursula (NIH/OD) [E] <ursula.koniges@nih.gov>
Cc: Plank-Bazinet, Jennifer (NIH/OD) [E] <jennifer.bazinet@nih.gov>; Fennington, Kelly (NIH/OD) [E] <fenningk@od.nih.gov>
Subject: RE: Drug Pricing BRAIN Record – Ursula Has Uploaded Into BRAIN

b5

From: Koniges, Ursula (NIH/OD) [E] <ursula.koniges@nih.gov>
Sent: Thursday, January 31, 2019 2:10 PM
To: Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>
Cc: Plank-Bazinet, Jennifer (NIH/OD) [E] <jennifer.bazinet@nih.gov>; Fennington, Kelly (NIH/OD) [E] <fenningk@od.nih.gov>
Subject: Drug Pricing BRAIN Record – Ursula Has Uploaded Into BRAIN

Hi Mark,

Just a quick FYI to loop you into where the Drug Pricing record is in the BRAIN review process. **I've uploaded the Lyric-reviewed Drug Pricing record into BRAIN for us**, so we're done with that.

Rationale: Jennifer and Kelly recommended that, due to time concerns, we should upload the Lyric-reviewed Drug Pricing brief into BRAIN ASAP, even though we're still waiting on comments from Carrie.

Follow-up Needed:

- If Carrie ends up recommending edits, I'll be happy to assist with incorporating those into the record later.
- Lyric had one question embedded in her review – **b5**

b5

Thanks,
-Ursula

From: Vathyam, Surekha (NIH/NCI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5ED61806C5BF4E9A819DDB37E91DEE70-VATHYAMS]
Sent: 7/31/2017 6:56:44 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]
Subject: FW: Request for Information and Comments on Prospective Grant of Exclusive Patent License: Composition and Methods for Delivering Inhibitory Oligonucleotides for the Treatment of Pancreatic Cancer, to VeriLuce Therapeutics ("VLT") located in Toronto, ON,
Attachments: Response to KEI Comments July 31 2017.pdf; KEI Comments July 22 2017 .pdf

Hi Mark,

I received the below response to the attached letter I sent to KEI today. I have attached the KEI letter sent on July 22 for reference. Please call me when you get the chance or let me know when would be a good time for a call.

Thanks,
Surekha

SUREKHA VATHYAM, Ph.D.
Senior Technology Transfer Manager,
National Cancer Institute Technology Transfer Center
Main: 240-276-5530
Direct: b6
Email: vathyams@mail.nih.gov

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From: b6 **On Behalf Of** Jamie Love
Sent: Monday, July 31, 2017 1:07 PM
To: Vathyam, Surekha (NIH/NCI) [E] <vathyams@mail.nih.gov>
Subject: Re: Request for Information and Comments on Prospective Grant of Exclusive Patent License: Composition and Methods for Delivering Inhibitory Oligonucleotides for the Treatment of Pancreatic Cancer, to VeriLuce Therapeutics ("VLT") located in Toronto, ON,

Thank you. What about our 13 requests for information? None of them are addressed in your brief letter of July 31, 2017 to us.

On Mon, Jul 31, 2017 at 11:57 AM, Vathyam, Surekha (NIH/NCI) [E] <vathyams@mail.nih.gov> wrote:

> Dear Mr. Love,
>
> Please find attached my response to KEI's comments regarding the above-referenced Federal Register notice.
>
> Regards,

Surekha

SUREKHA VATHYAM, Ph.D.

Senior Technology Transfer Manager,

National Cancer Institute Technology Transfer Center

Main: 240-276-5530

Direct b6

Email: vathyams@mail.nih.gov

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From: b6 **On Behalf Of** Jamie Love
Sent: Saturday, July 22, 2017 8:07 AM
To: Vathyam, Surekha (NIH/NCI) [E] <vathyams@mail.nih.gov>
Subject: Request for Information and Comments on Prospective Grant of Exclusive Patent License: Composition and Methods for Delivering Inhibitory Oligonucleotides for the Treatment of Pancreatic Cancer, to VeriLuce Therapeutics ("VLT") located in Toronto, ON, C...

Dear Dr. Vathyam,

Attached is a PDF of a letter responding to the Federal Register on July 10, 2017, document citation: 82 FR 31783, regarding a license on patents for the treatment of pancreatic cancer, to VeriLuce Therapeutics, located in Toronto, Ontario, Canada.

Jamie

--

James Love. Knowledge Ecology International
http://www.keionline.org/donate.html

> KEI DC tel: +1.202.332.2670, US Mobile: b6 Geneva Mobile: b6
> twitter.com/jamie_love

--
James Love. Knowledge Ecology International
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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health/ NCI
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Office (240) 276-5530
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July 31, 2017

James Love
Knowledge Ecology International
1621 Connecticut Avenue, Suite 500
Washington, DC 20009
(202)332-2670
James.love@keionline.org

SUBJECT: KEI Comments in Regards to 82 FR 31783, "*Prospective Grant of Exclusive Patent License: Composition and Methods for Delivering Inhibitory Oligonucleotides for the Treatment of Pancreatic Cancer*" notice – Prospective Exclusive Patent License to VeriLuce Therapeutics

Dear Mr. Love,

Thank you for providing KEI comments to the recent *Federal Register* Notice referenced above regarding the National Institute on Aging's proposed intent to grant an Exclusive Patent License to VeriLuce Therapeutics. Prior to posting a notice for a proposed grant of an Exclusive Patent License, the National Institute of Health (NIH) determines that the criteria set forth in 37 CFR 404.7 have been satisfied with respect to granting the organization an exclusive license of the Government's intellectual property in the field of use as specified. The notice period provides an opportunity for public comment and possible objection to the proposed license. We consider all comments prior to negotiating the proposed license and will consider your comments.

Best regards,

Surekha Vathyam, Ph.D.
Senior Technology Transfer Manager,
National Cancer Institute Technology Transfer Center
9609 Medical Center Dr., Room 1E-530, MSC 9702
Rockville, MD 20850-9702
Phone: 240-276-5530
Email: vathyams@mail.nih.gov

KEI
KNOWLEDGE ECOLOGY
INTERNATIONAL

July 22, 2017

Surekha Vathyam, Ph.D.,
Senior Technology Transfer Manager,
NCI Technology Transfer Center,
9609 Medical Center Drive,
RM 1E530 MSC 9702,
Bethesda, MD 20892-9702 (for business mail),
Rockville, MD 20850-9702
Telephone: (240) 276-5530
Facsimile: (240) 276-5504

Via Email: vathyams@mail.nih.gov

Re: Request for Information and Comments on Prospective Grant of Exclusive Patent License: Composition and Methods for Delivering Inhibitory Oligonucleotides for the Treatment of Pancreatic Cancer, to VeriLuce Therapeutics ("VLT") located in Toronto, ON, Canada.

Dear Dr. Vathyam,

I am writing to request information and to provide comments regarding the proposed exclusive patent license noticed in the Federal Register on July 10, 2017, document citation: 82 FR 31783, regarding the treatment of pancreatic cancer, to VeriLuce Therapeutics, located in Toronto, Ontario, Canada.

VeriLuce does not seem like a big company. It's web page is just a single page which provides almost no information about the company leadership or its experience in product development. The entire contents of the web page are as follows:

> *VeriLuce Therapeutics - A DRUG DEVELOPMENT COMPANY*
>
> *VeriLuce Therapeutics in-licenses compounds in pre-clinical stage of development and progresses them to early clinical for divestment or further development through collaboration with other Companies*
>
> *About Us*

> *We are a team of dedicated and experienced individuals who are passionate about drug development and about improving the lives of patients; Our experience spans from scientific research and medical to regulatory and business development; We are currently focusing our efforts in seeking, in-licensing and developing compounds that treat rare oncology diseases.*
>
> *Licensing and Collaborations*
>
> *We are seeking licensing and collaboration opportunities in the area of oncology. Please contact us to discuss potential current and future opportunities.*
>
> *Contact Us: elena.frigerio@verilucetherapeutics.com 647-965-1*

According to Linkedin, the company was founded in 2015, and has 1-10 employees.

It is not clear how a company located in Canada with almost no track record and very few employees was selected to obtain an exclusive license to a portfolio of United States owned patents relating to pancreatic cancer.

My requests for information are as follows:

1. Who are the principals in Veriluce Therapeutics?
2. Why did the NIH select Veriluce Therapeutics for an exclusive license?
3. Is the NIH giving Veriluce Therapeutics the opportunity to obtain exclusive rights in order to market the patents to a bigger more capable firm?
4. Are any of the personnel in Veriluce former NIH employees or relatives or business partners of NIH employees?
5. Are the patent applications public, and if not, can you share them?
6. How many companies have expressed interest in licensing the patents?
7. What is the term of the proposed license?
8. What is the royalty obligation?
9. How much money did the federal government spend on the development of this technology?
10. How much money has VeriLuce invested in the technology?
11. What has VeriLuce promised to do as regards investments in the development of products based upon the patented inventions?
12. Did the NIH propose any provisions in the license that would protect US residents from paying high prices on products, or ensure access in developing countries, and if so, can you share the proposals and the response by the VeriLuce?
13. Please provide a copy of all CRADA agreements, if any, between the NIH and VeriLuce.

KEI proposes the NIH include the following measures in the license to address the pricing and availability of products based upon the patented invention:

1. The lessee agrees to make products based upon the invention available to the public in the United States at prices [that are reasonable, and in any case] no higher than the median price charged in the seven countries with the largest GDP, that have per capita incomes of at least half that of the United States.

2. The lessee is expected to either (a) register and make available the products based upon the invention in developing countries at an affordable price and with sufficient quantities, or (b) offer sufficient technology transfer and rights in intellectual property for third parties to provide the products on a competitive basis.

KEI proposes the NIH undertake the following measures to address transparency.

1. Provide some information on who runs and owns the company and why the company was selected.

2. Require the lessee to provide a report annually that will be made available to the public without redaction that provides the following information.
   a. Expenditures on specific clinical trials,
   b. Average prices and revenues in every national market,
   c. All government subsidies for the development of the product,
   d. All outlays on marketing the product, by national market.

3. Make public an unredacted copy of the license agreement and any associated CRADA. This was the practice earlier at the NIH, and which is the current practice of some companies when they provide disclosures to shareholders through the SEC. These patents were funded by the U.S. taxpayers, and the public has the right to see the terms of the exclusive license to this unknown Canadian firm.

Thank you.

James P Love

James Love
Knowledge Ecology International
1621 Connecticut Avenue, Suite 500
Washington, DC 20009
http://www.keionline.org | mailto:james.love@keionline.org

From: Lambertson, David (NIH/NCI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=3C95B34F709746A8A2553CE54E74ACE2-LAMBERTSOND]
Sent: 6/21/2018 7:54:13 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]
CC: Rodriguez, Richard (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8092cb5394e04733ac0d4d84d25f65e5-rodrigr]
Subject: RE: quick question from a journalist

I think the response is okay, but I offer some suggestions below (in red) for consideration.

David A. Lambertson, Ph.D.
Senior Technology Transfer Manager
Technology Transfer Center
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david.lambertson@nih.gov
http://ttc.nci.nih.gov/

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From: Rohrbaugh, Mark (NIH/OD) [E]
Sent: Thursday, June 21, 2018 3:44 PM
To: Lambertson, David (NIH/NCI) [E] <david.lambertson@nih.gov>
Cc: Rodriguez, Richard (NIH/NCI) [E] <richard.rodriguez@nih.gov>
Subject: RE: quick question from a journalist

How does this sound as a response to the reporter from OC. They have worked with him before and I have interviewed with him.

b5

From: Lambertson, David (NIH/NCI) [E]
Sent: Thursday, June 21, 2018 3:16 PM
To: Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>

Cc: Rodriguez, Richard (NIH/NCI) [E] <richard.rodriguez@nih.gov>
Subject: RE: quick question from a journalist

b5

Let me know if you need any other details.

David A. Lambertson, Ph.D.
Senior Technology Transfer Manager
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david.lambertson@nih.gov
http://ttc.nci.nih.gov/

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From: Rohrbaugh, Mark (NIH/OD) [E]
Sent: Thursday, June 21, 2018 3:09 PM
To: Lambertson, David (NIH/NCI) [E] <david.lambertson@nih.gov>
Cc: Rodriguez, Richard (NIH/NCI) [E] <richard.rodriguez@nih.gov>
Subject: RE: quick question from a journalist

b5

From: Lambertson, David (NIH/NCI) [E]
Sent: Thursday, June 21, 2018 3:05 PM
To: Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>
Cc: Rodriguez, Richard (NIH/NCI) [E] <richard.rodriguez@nih.gov>
Subject: FW: quick question from a journalist

Hi Mark,

I also received this question from a non-KEI entity. b5

Thanks,

David A. Lambertson, Ph.D.
Senior Technology Transfer Manager
Technology Transfer Center
National Cancer Institute/NIH
david.lambertson@nih.gov
http://ttc.nci.nih.gov/

9609 Medical Center Drive, Rm 1-E530 MSC 9702
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From: Silverman, Ed [mailto:ed.silverman@statnews.com]
Sent: Thursday, June 21, 2018 11:25 AM
To: Lambertson, David (NIH/NCI) [E] <david.lambertson@nih.gov>
Subject: quick question from a journalist

Hi Dave,

My name is Ed Silverman and I run the Pharmalot blog at The Boston Globe's STAT health news site, where I track the pharmaceutical industry.

A quick question about the NIH notice to provide a license to Beoro Therapeutics for a cancer drug...

https://www.federalregister.gov/documents/2018/06/07/2018-12179/prospective-grant-of-an-exclusive-patent-license-the-development-of-an-anti-bcma-immunotoxin-for-the

There's not a lot of publicly available information about Beoro and wondering why the agency chose this company. What info exists to give taxpayers confidence that such a license would be awarded to a company with the expertise and capabilities to develop the technology?

It seems one of the Beoro folks - Gerhard Niederfellner - worked at Roche. Can you confirm this and provide some insight into how this company was chosen?

Thanks
ed silverman
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From: Plude, Denise (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/CN=RECIPIENTS/CN=PARKSDE]
Sent: 4/24/2017 6:52:27 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=OD/cn=ROHRBAUM]
CC: Wertz, Jennifer (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=Recipients/cn=wertzj]
Subject: WF 357204 - Response Creation due 5/1
Attachments: 1a KEI-March_10_2017-3rd-Comments-Zika.pdf; 1b KEI-UACT-April_19_2017-Xtandi-Appeal.pdf; 1c Xtandi-March-In-Request-Letter-14Jan2016.pdf; Request for Reevaluation of Xtandi Bayh Dole Petition

Work Folder Information

Work Folder: WF 357204
Process: Response Creation
Program Analyst: Hurlebaus, Lisa (NIH/OD) [E]
Due Date: May 01, 2017
WF Subject: OS assignment. KEI & UACT write about the prostate cancer drug, Xtandi (enzalutamide). Asks the Government to reconsider the decision not to use the 'march-in' rights, under the Bayh-Dole Act, for this excessively-priced drug. (AS-760889)
IC: od_osp
From: Goldman, Andrew
To: Price, TomMattis, Jim
Remarks: OS assignment. Note to OER & OSP: Please work together to prepare Direct Reply response. You should decide/recommend who should sign draft response (Dr. Lauer or Dr. Wolinetz; or someone else?). Please provide draft response to Exec Sec in DDRMS by 12:00pm, Monday, May 1, for OD clearances. Thanks very much, Lisa Hurlebaus

KEI
KNOWLEDGE ECOLOGY
INTERNATIONAL

March 10, 2017

Commander
U.S. Army Medical Research and Materiel Command
ATTN: Command Judge Advocate
MCMR-JA, 504 Scott Street
Fort Detrick, MD 21702-5012
Via Fax: +1 (301) 619-5034
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Dear Command Judge Advocate:

This is the third set of comments signed or cosigned by KEI, including our comments on December 21, 2017 and the joint NGO comments January 12, 2017, with regards to the grant of an exclusive license of patents on a Zika Vaccine by the U.S. Army to Sanofi.[1]

Before responding to the question of the license itself, we offer this comment on the process. We had hoped to obtain answers to several questions about the proposed license, but none have been forthcoming from the Army. Whose interests are served by the lack of transparency: the large French drug and vaccine manufacturer Sanofi, or the U.S. taxpayers and residents who pay for the Army's research budget, and will have to pay if the vaccine is approved by the FDA? The lack of transparency seems to be designed to protect the French company from efforts to avoid compliance with the provisions of 35 U.S.C. § 209 and 35 U.S.C. § 201(f), and to protect the Army from informed criticism of the decision to grant an exclusive license, or their terms.

Our comments today address the issue of the statutory definition of "practical application."

The Army is required to evaluate, before granting an exclusive license on a patent, whether the licensee will bring the invention to "practical application," which is further defined in the Bayh-Dole Act as requiring that the licensee make the invention "available to the public on reasonable terms."[2] As we detail in this submission, courts and other fora in the United States, the United Kingdom, South Africa, and the World Trade Organization all have taken the position that "reasonable terms" includes, logically, considerations of price.

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[1] Department of the Army, Intent To Grant an Exclusive License of U.S. Government-Owned Patents, 82 Fed. Reg. 8611 (Jan. 27, 2017); Department of the Army, Intent To Grant an Exclusive License of U.S. Government-Owned Patents, 81 Fed. Reg. 89087 (Dec. 9, 2016).
[2] 35 U.S.C. § 201(f).

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Practical Application

The term "practical application" is mentioned seven times in 35 U.S.C. § 209 as a condition for the grant of an exclusive license on a federally-owned patent, including:

- once in § 209(a)(1)(A),
- twice in § 209(a)(2),
- once in § 209(a)(3),
- once in § 209(c) and,
- twice in § 209(d)(3)(A).

Practical application is defined in 35 U.S.C. 201(f) as follows:

> (f) The term "practical application" means to manufacture in the case of a composition or product, to practice in the case of a process or method, or to operate in the case of a machine or system; and, in each case, under such conditions as to establish that the invention is being utilized and *that its benefits are to the extent permitted by law or Government regulations available to the public on reasonable terms*. (Emphasis added.)

"Available to the public on reasonable terms" is thus a statutory requirement.

The definition is not simply "available to the public." The definition is "available to the public on reasonable terms." When an agency only requires a product to be available on any terms, including at unreasonable prices, the public is denied the protection that the statute seeks to offer.

Statements by Former Senators Bayh and Dole Regarding Reasonable Terms

Some patent holders have argued that “available to the public on reasonable terms” does not have anything to do with the price — as if there is some other set of terms that excludes price that are covered by the statute. In support of this view, rights holders have referred to statements by former Senators Birch Bayh and Bob Dole, including an April 2002 letter to the Editor of the Washington Post,[3] signed by both, and a statement by Senator Bayh at an NIH meeting on the 2004 request for the use of march-in rights on the patents on the HIV drug ritonavir.[4]

The notion that “available to the public on reasonable terms” does not extend to the price is itself an unreasonable interpretation of the plain language of the statute, which is anchored by the context of “available to the public.” Why would Senators Dole and Bayh make that argument? Like many former members of Congress, both Dole and Bayh took lucrative jobs in Washington, DC, to influence the Congress and the Executive branch. Both have several commercial conflicts. In Senator Bayh’s case, he has even argued more than one side of the issue, depending upon who, at the time, was paying him.

Bob Dole joined the law and lobbying firm Verner, Liipfert in 1997. In 1998, Pfizer hired Dole to promote the use of Viagra.[5] In 2000, Bob Dole also filed lobbyist reports for Bob Dole Enterprises. From 2000 to 2002, Bob Dole Enterprises listed the pharmaceutical company Johnson and Johnson as its largest client, paying $820,000 in fees in three years.

Senator Bayh also became a lobbyist and a paid influencer after leaving the senate in 1981.

In 1997, Bayh was hired by Cellpro, Inc. — a small Washington State firm manufacturing an FDA medical device that was used in bone marrow transplants — to pursue a march-in case against Johns Hopkins University over NIH-funded patents. In a March 3, 1997 petition, Birch Bayh and Lloyd N. Cutler (who had served as White House Counsel for Jimmy Carter and Bill Clinton) asked Health and Human Services Secretary Donna E. Shalala to grant a march-in license to CellPro. The petition focused on the obligation to set “reasonable terms” in the licensing of the invention, and the impact of the licensing decisions on the prices faced by consumers. Bayh and Cutler wrote that “the interests of the public which paid for the research that led to the patents and is now being asked to pay again — cry out for a far lower royalty payment by CellPro.” The petition also made reference to royalty layering as “a common problem that leads to unreasonably high royalties (and prices of medical care) that should be dealt with by regulation."[6] They wrote:

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[3] Birch Bayh and Robert Dole, “Our Law Helps Patients Get New Drugs Sooner,” *Washington Post*, A28 (Apr. 11, 2002).

[4] Statement of Senator Birch Bayh to the National Institutes of Health, May 25, 2004, available at: http://www.essentialinventions.org/drug/nih05252004/birchbayh.pdf

[5] “Pfizer Hires Bob Dole for TV Ad Campaign,” Associated Press, December 12, 1998, available at: http://articles.latimes.com/1998/dec/12/business/fi-53139

> "CellPro submits that there may well be reason for the government to adopt regulations covering situations like the present where the same product may be claimed to be covered by patents arising out of work done by more than one federal grantee. Moreover, investigation may be needed to determine whether the royalty "layering" that plainly exists in the present case -- where federal grantee Johns Hopkins has licensed to Becton Dickinson, which apparently marked up the price and relicensed to Baxter, which in turn clearly marked up the price and relicensed to Systemix and Applied Immune Systems -- is a common problem that leads to unreasonably high royalties (and prices of medical care) that should be dealt with by regulation."

On June 14, 2001, Birch Bayh joined Venable, Baetjer, Howard & Civiletti as a partner, where he focused on "the firm's growing public policy advocacy practice." The following year, Bayh joined Dole in writing a letter to the editor of the Washington Post attacking the notion expressed by Professors Peter Arno and Michael Davis — argued in a March 27, 2002 Washington Post editorial[7] — that "available to the public on reasonable terms" includes a requirement to set "reasonable prices."

Bayh also took this position in the 2004 ritonavir march-in case, when he claimed that he was not paid to provide evidence in the hearing. But, Bayh did not disclose that Venable, the firm where he was a partner, represented Abbott, the holder of the ritonavir patents. Bayh would continue to appear on behalf of the firm to give evidence of what the Bayh-Dole Act meant, including, for example, in a December 23, 2010 amicus brief in *Stanford University v. Roche Molecular Systems*,[8] where the Supreme Court rejected Bayh's interpretation.[9]

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[6] Lloyd N. Cutler and Birch Bayh, Letter to Secretary of Health and Human Services Donna E. Shalala, March 3, 1997, available at: https://ia800409.us.archive.org/19/items/nih_cellpro/foia_cellpro1.pdf.

[7] Peter Arno and Michael Davis, "Paying Twice for the Same Drugs," *Washington Post*, A21, Mar. 27, 2002, https://www.washingtonpost.com/archive/opinions/2002/03/27/paying-twice-for-the-same-drugs/c031aa41-caaf-450d-a95f-c072f6998931/; Peter Arno and Michael Davis, *Why Don't We Enforce Existing Drug Price Controls? The Unrecognized and Unenforced Reasonable Pricing Requirements Imposed upon Patents Deriving in Whole or in Part from Federally Funded Research*, 75 Tulane L. Rev. 631-98 (2000).

[8] Brief of Birch Bayh as *Amicus Curiae* in Support of Petitioner (Dec. 23, 2010), *Stanford Univ. v. Roche Molecular Systems, Inc.*, 563 U.S. 776 (2011), available at: https://ogc.stanford.edu/sites/default/files/brief_amicus_curiae_of_birch_bayh_december_23_2010.pdf; John F. Cooney and Michael A. Gollin, *Venable team files Amicus Brief for Senator Bayh in support of Bayh-Dole Act in Stanford v. Roche*, January 14, 2011, available at: https://www.venable.com/venable-team-files-amicus-brief-for-senator-bayh-in-support-of-bayh-dole-act-in-istanford-v-rochei-01-14-2011/.

[9] *Stanford Univ. v. Roche Molecular Systems, Inc.*, 563 U.S. 776 (2011); James E. Nelson and Stephanie T. Anelli, *Stanford v. Roche: The Importance of Precise Contract Drafting*, Venable (July 2011), https://www.venable.com/files/Publication/cef85449-cb09-463a-ab1e-26f57aa40ffc/Preview/PublicationAttachment/257797c5-1f44-46c8-a8be-375f530357eb/Stanford_Roche_7-19-11.pdf

Bayh argued in 2004 that Arno and Davis misinterpreted the legislative history of the Bayh-Dole Act as regards protections against unreasonable prices.[10] However, Bayh's criticism focused on the nuances of the legislative history of the march-in provisions of the Bayh-Dole Act (35 U.S.C. § 203), and not the arguments made by Arno and Davis with regards to the way that the courts have interpreted "reasonable terms" to include a "reasonable price." And, while Bayh's written submission for the ritonavir case is correct to point out that the section of the Committee report (S. Rep. No. 96-480) on S. 414 (which became the Bayh-Dole Act) that addresses "windfall profits" does not apply to the current march-in rights provision, he does not address the definition of "practical application." Bayh also acknowledged that there were concerns about patent owners taking unfair advantage of the government-funded patent rights, a topic for which the march-in provision was often cited as a remedy in the discussion of more than one bill on government-funded patent rights.

In further evaluating the legislative history of the march-in provision, Bayh stated that Arno and Davis misquoted an exchange at a 1979 Committee hearing on S. 414 between himself and the Comptroller General of the United States, Elmer Staats, to imply that Bayh believed that the intention of the march-in provision of the bill was to prevent "the large, wealthy corporation to take advantage of Government research dollars and thus to profit at the taxpayers' expense." Bayh is correct to note that this statement was not made with explicit reference to the march-in provision, however, as Bayh himself noted in his own 2004 testimony on the ritonavir case, he stated in his 1979 testimony that he believed that, overall, "We thought we had drafted this bill in such a way that this was not possible." Moreover, neither his statement nor Staats' addressed the definition of "reasonable terms" or the prices of patented inventions.[11] Thus, it appears that, in 1979, Bayh did believe that the bill was drafted to prevent "corporations [taking] advantage of Government research dollars" and from unduly "profit[ing] at the taxpayer's expense," a position he also took in the 1997 Cellpro case (see above), where he expressed concern over the impact of the patent licensing terms on the prices charged to consumers.

Bayh also argued that the NIH has concluded that reasonable pricing requirements in relation to industry collaborations is contrary to the Bayh-Dole Act. The NIH language he quotes — from a non-binding report issued 21 years after the passage of the Bayh-Dole Act — does not, however, make any legal conclusions, but rather argues that the Bayh-Dole Act should be interpreted in light of present-day policy realities.

Reasonable Terms in U.S. Case Law

"Reasonable terms" has been regularly interpreted in case law in both federal and state courts to include price.

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[10] Statement of Senator Birch Bayh to the National Institutes of Health, May 25, 2004. Available at: http://www.essentialinventions.org/drug/nih05252004/birchbayh.pdf

[11] *The University and Small Business Patent Procedures Act*, Hearings before the S. Comm. on the Judiciary on S. 414, 96 Cong. 44 (May 16, 1979).

In *American Liberty Oil Co. v. Fed. Power Comm'n*, the Fifth Circuit Court of Appeals interpreted the Natural Gas Act's provision allowing the Federal Power Commission to establish "reasonable terms and conditions" as including price.[12] *See also*, *United States v. Mississippi Vocational Rehab. for the Blind*, 812 F. Supp. 85, 87-89 (S.D. Miss. 1992) (interpreting 20 U.S.C. § 107d-3 provision allowing for federal entities to negotiate reasonable terms as including price).

In a case regarding the abuse of monopoly power, the Sixth Circuit Court of Appeals in *Byars v. Bluff City News Co.* stated that "The difficulty of setting reasonable terms, especially price, should be a substantial factor when confronted with the latter situation."[13]

In *Topps Chewing Gum, Inc. v. Major League Baseball Players Ass'n*, 641 F. Supp. 1179 (S.D.N.Y. 1986), an antitrust case, the Court recounted facts on the record, including a willingness of the players association to negotiate a license on "commercially reasonable terms," which the Court "assume[d] means at a price higher than Topps currently pays under its player contracts." *Id.* at 1191.

In contractual and commercial matters governed by the Uniform Commercial Code, Art. 9, § 610, on the disposition of collateral after default, contains an official comment on the "Relevance of Price" that suggests that price may not allow for a per se violation, but is to be considered: "While not itself sufficient to establish a violation of this Part, a low price suggests that a court should scrutinize carefully all aspects of a disposition to ensure that each aspect was commercially reasonable." See also *68A Am. Jur. 2d Secured Transactions* § 646 (1993) (stating that price is a term of commercial reasonableness, but low price alone will not render a sale commercially unreasonable).

Under the proceeds test under Article 9, some courts have accordingly held that price is a term of commercial reasonableness. *See, e.g.*, *ITT Indus. Credit Co. v. Chasse*, 25 U.C.C. Rep. Serv. (CBC) 914, 917-18 (Conn. Super. Ct. 1978); *Farmers Bank v. Hubbard*, 276 S.E.2d 622, 626-27 (Ga. 1981) (price is term of commercial reasonableness that secured party must establish is fair and reasonable); *McMillian v. Bank S., N.A.*, 373 S.E.2d 61, 62 (Ga. Ct. App. 1988) (sale's method and manner were commercially reasonable, but that price was a "term"); *FDIC v. Herald Square Fabrics Corp.*, 439 N.Y.S.2d 944, 955 n.8 (N.Y. App. Div. 1981) (stating that a "wide or marked discrepancy in disposal and sale prices is an independently adequate reason to question the commercial reasonableness of a disposition").

Reasonable Terms in U.K. Patent Law

In the United Kingdom, the Patents Act 1977 includes a "reasonable terms" requirement in § 48A, on compulsory licensing in the case of WTO proprietors, providing for the ability to obtain compulsory licenses in cases where “demand in the United Kingdom for that [patented] product is not being met on reasonable terms,” or for a refusal to license on reasonable terms.[14] The U.K. Manual of Patent Practice, an official government document provided by the Intellectual Property Office, explains that the requirement of reasonable terms is meant to contemplate price:

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[12] 301 F.2d 15 (5th Cir. 1962).

[13] 609 F.2d 843, n.58 (6th Cir. 1979).

> **48A.03**
> The applicant needs to show that such a demand is not being met on reasonable terms. What constitutes “reasonable terms” depends on a careful consideration of all the surrounding circumstances in each case, eg the nature of the invention, the terms of any licences under the patent, the expenditure and liabilities of the patentee in respect of the patent, and the requirements of the purchasing public. The price charged by the patentee should be a bona fide one and not one adopted to suppress or depress demand.[15]

The Manual of Patent Practice cites the case of *Brownie Wireless Co Ltd's Applications* (1929) 46 RPC 457 as instructive. In that case, the Court addressed the question of reasonable terms in a case involving a refusal to license patents used for radio amplifiers. The case involved a prior version of the UK patent law (§ 27 of the Patents and Designs Act 1907 and 1919), which provided for compulsory licenses in cases of an abuse of the patent right, explicitly including excessive pricing.[16] The Court stated that “reasonable terms” was an “elastic phrase:”

> The grant of the licence which is refused must be a grant "on reasonable terms", an elastic phrase which can only be construed with certainty with reference to the actual facts of each particular case. No one can hope to lay down any exhaustive rules to enable the question whether the terms of a proposed licence are reasonable or not to be answered with certainty in every case. The answer to the question must in each case depend on the careful consideration of all the surrounding circumstances. The nature of the invention covered by the patent, the terms of the licences (if any) already granted, the expenditure and liabilities of the patentee in respect of the patent, the requirements of the purchasing public, and so on.[17]

In the case of *Cathro's Application* (1934) 51 RPC 75, the Court addressed an application for a compulsory license of patents pertaining to electric valves, on grounds that demand was not being met on reasonable terms under § 27 of the Patents and Designs Acts 1907 to 1932.[18] The Court cited *Brownie Wireless*, stating:

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[14] The Patents Act, 1977 (as amended), Section 48A(1)(a)-(b).

[15] The Manual of Patent Practice is available at https://www.gov.uk/guidance/manual-of-patent-practice-mopp.

[16] *Brownie Wireless Co Ltd's Applications* (1929) 46 RPC 457. Available at https://goo.gl/oK9KBY.

[17] *Id.* at 473.

[18] *Cathro's Application* (1934) 51 RPC 75. Available at https://goo.gl/FUbKe2.

> Now I think in the first place that the expression "on reasonable terms" in paragraph (c) refers mainly to the price charged for the patented article, and I am fortified in this view by a consideration of the summary of the kinds of abuses dealt with by Section 27 given by Mr. Justice Luxmoore in Brownie Wireless Company's Applications (46 RP.C. at page 471) where the reference to "excessive price" (see line 31) clearly refers to the abuse covered by paragraph (c). No doubt, however, this statement of the 30 learned Judge should not be considered to be exhaustive as to the scope of the paragraph, and it may be that in some cases other terms than those referring merely to price should be taken into account.[19]

Reasonable Terms in South African Patent Law

South Africa has a similar provision in its patent law for compulsory licenses where there has been an abuse of the patent right, including where "demand for the patented article in the Republic is not being met to an adequate extent and on reasonable terms."[20]

In a case on this issue, *Afitra Ltd v. Carlton Paper of SA* 1992 BP 331, the Court of the Commissioner of Patents referred to the UK decisions in *Cathro's Application* and *Brownie Wireless* among others as being persuasive, and held that "on the charge of not granting a licence, the Court should be provided with evidence indicating, with reasonable precision, what reasonable terms are."[21] While the compulsory license in that case was denied, it failed because the petitioner had not met its evidentiary burden of demonstrating the price to be unreasonable.

Reasonable Terms as Interpreted by the World Trade Organization

In the dispute settlement case of Mexico-Telecoms brought before the World Trade Organization (case DS204), the WTO addressed the question of what constituted "reasonable terms." The complaint brought by the United States alleged, *inter alia*, that Mexico had violated its commitments under GATS by failing to ensure access to and use of public telecommunications transport networks and services on reasonable and non-discriminatory terms and conditions for the supply of basic and value-added telecommunications services.[22]

The United States put forward an argument regarding restricted supply directly linked to pricing:

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[19] *Id.* at

[20] Patents Act No. 57 of 1978, section 56(2)(c). Available at http://www.cipc.co.za/files/9513/9452/7965/Patent_Act.pdf.

[21] *Afitra Ltd v. Carlton Paper of SA* 1992 BP 331, available at http://www.wipo.int/scp/en/exceptions/replies/safrica.html.

[22] Available at https://www.wto.org/english/tratop_e/dispu_e/cases_e/ds204_e.htm.

> IV.230 In terms of the context, the United States argues that the interconnection obligations of Section 2 are especially important for the cross-border supply of basic telecom services – particularly in markets like Mexico, which legally bar foreign service suppliers from owning facilities and therefore force foreign suppliers to rely on the major supplier to deliver their services to the end-user. In such cases, foreign suppliers have no choice but to pay a domestic service supplier (such as Telmex) an interconnection rate to terminate their calls. As a result, the major supplier has the power and incentive to price this input at levels which extract as much revenue as possible from cross-border suppliers. Thus, by raising the wholesale price of cross-border interconnection, the major supplier has the power to raise the retail price, reduce demand for the retail service, and thereby restrict the cross-border supply of services into Mexico.

The Panel found that “terms” would implicitly include pricing elements:

> VII.325 As discussed in part B of these findings, the words "terms and conditions" may have many meanings. In relation to contracts and agreements, the word "terms" is defined to mean "conditions, obligations, rights, price, etc., as specified in contract or instrument", while "condition" is defined, inter alia, as "a provision in a will, contract, etc., on which the force or effect of the document depends". **Although the words "terms" and "conditions" are closely related, and are frequently used concurrently, the ordinary meaning of the word "terms" suggests that it would include pricing elements, including rates charged for access to and use of public telecommunications transport networks and services.** (Emphasis added.)

Conclusion

In our past submissions, provided as separate attachments along with this letter, we have argued that an exclusive license in this case is contrary to provisions in the Bayh-Dole Act that require that the Army evaluate the “reasonable and necessary” incentives required by Sanofi. Sanofi already receives significant funding from the government to conduct clinical trials, has a CRADA with the Army, and would receive both significant data exclusivity protections and a priority review voucher for successfully bringing a Zika vaccine to market.

If, however, the Army decides to grant an exclusive license, it has a clear obligation to ensure that the license includes terms that provide for a reasonable price.

We request a meeting to discuss these issues with you in further detail.

Sincerely,

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KEI
KNOWLEDGE ECOLOGY INTERNATIONAL

UACT
UNION FOR AFFORDABLE CANCER TREATMENT

April 19, 2017

The Honorable Tom Price, M.D.
Secretary
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201
Via: Thomas.Price@hhs.gov

The Honorable Jim Mattis
Secretary
Department of Defense
1400 Defense Pentagon
Washington, D.C. 20301-1400
Via: whs.pentagon.esd.mbx.cmd-correspondence@mail.mil

Dear Secretaries Price and Mattis:

Knowledge Ecology International (KEI) is a non-profit organization with offices in Washington, DC. The Union for Affordable Cancer Treatment (UACT) is a non-profit cancer patient group. More about each group is available on their respective web pages: http://keionline.org and http://cancerunion.org.

This letter is to request that the United States Government reconsider the decision of the Obama Administration to deny our petition, initially filed in January 2016, that the government use its rights in patents under the Bayh Dole Act (35 U.S.C. §§ 200 *et seq.*) for the excessively-priced, blockbuster drug enzalutamide (marketed by Astellas Pharma as Xtandi). The initial petition highlighted the possibility of using either march-in rights under 35 U.S.C. § 203, or the royalty-free rights in the patents under 35 U.S.C. § 202(c)(4), in order to allow for generic competition and more affordable prices. The petition is attached.

The failure to act on behalf of the American people in this case was a deliberate choice made by the previous administration, to accept an outcome that has U.S. residents paying far more than any other country for a drug invented with taxpayer funding.

Given the Trump Administration's promise to make great deals for American citizens, we believe that this case is well-suited to review with new attention. In short, does the Trump administration support a policy that Americans will pay more than patients in any other country on the planet for a medicine that was created with American tax dollars?

In the initial petition, HHS was urged to act to permit competition in the supply of the drug when the prices in the United States were higher than the median prices of countries with comparable incomes and large economies.

Moreover, in addition to the policy that the U.S. should not pay higher prices than other high income countries, the HHS should also have a policy to address the cases where high prices outside of the United States present access barriers, for example, in developing countries where prices are excessive and incomes are low.

The KEI/UACT Xtandi Petition

The 26-page KEI/UACT petition focused on the fact that Astellas Pharma, a Japanese corporation, is currently charging American citizens more than $130,000 per patient per year for Xtandi, an effective and important medicine for prostate cancer. That price is more than any other country in the world, and three to four times the price charged in other high-income industrialized countries, including Japan. The excessive price is in spite of the fact that the drug was developed using U.S. taxpayer money via grants from the National Institutes of Health (NIH) and the Department of Defense.

We also noted that the cost of Xtandi to Medicare has ballooned in recent years, up from $34.9 million in 2012 to over $447 million in 2014. In 2015, Medicare paid a total of over $790 million for Xtandi, representing 69% of U.S. sales and 41% of global sales for the drug. Sales of Xtandi are projected to increase substantially in the coming years.

Finally, we argued that those high prices have resulted in high copayments and limited access for patients in the United States, including those who receive prescription drug benefits through Medicare.[1]

The KEI/UACT petition drew a significant amount of attention and support, including: a bicameral letter of support from six members of the House of Representatives and six members of the Senate; a letter of support from over fifty international non-governmental organizations; and many articles in a wide variety of media publications.[2]

In June 2016, Director Collins rejected the KEI/UACT petition in a two-page letter, failing to address the argument regarding high prices, and instead grounding the rejection on the absence of evidence of shortage of supply. He stated that the petition "provides no information and no information was provided from public sources to suggest that enzalutamide is currently or will be in short supply."

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[1] See: http://keionline.org/node/2485.

[2] For a comprehensive set of materials and documents relating to the KEI/UACT petition, see http://keionline.org/xtandi.

KEI/UACT never argued that shortage of supply was the issue; the issue was then and remains now that a Japanese corporation is charging Americans an excessive amount, far more than anywhere else in the world, to the detriment of American patients and taxpayers. The rejection thus failed to contend with a central point of the petition — that the excessive, discriminatory prices of Xtandi are unreasonable. Director Collins also neglected to explain why the federal government should not use the royalty-free rights in the patents to address the pricing abuses. The royalty free rights are a separate provision under the Bayh Dole Act that the government may use at any time, for any reason, and without precondition, on federally-funded inventions.

KEI filed comments with the Department of the Army in a separate proceeding that are germane to this issue, and are attached here for consideration with the Xtandi petition.[3] In those comments, KEI addressed the statutory phrase "practical application," defined under 35 U.S.C. § 201(f) to include "available to the public on reasonable terms," including a discussion of the contradictory statements made by Senators Birch and Dole during their post-Senate careers on the relationship between the term "available to the public on reasonable terms" and the price the public pays. This attached submission also provided examples where the term "reasonable terms" was interpreted to include price.

Revisiting the Petition under the Trump Administration

President Trump has rightfully spoken many times about the problem of outrageous drug prices, both during his campaign and after. In January 2017, President Trump stated that the pharmaceutical industry was "getting away with murder,"[4] and in his address to Congress again focused on the problem of high drug prices and his intent to "bring them down immediately."[5]

President Trump's statements echo the sentiments of a broad bipartisan consensus across the country. In a widely reported public opinion poll from October 2016, 74 percent of the American public viewed making high-cost drugs for chronic conditions affordable as a top priority for the incoming administration and Congress, and a majority of the public likewise said that government action to lower prescription drug prices was a top priority.[6]

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[3] KEI's comments can also be viewed here: http://keionline.org/sites/default/files/KEI-March_10_2017-3rd-Comments-Zika.pdf.

[4] http://www.reuters.com/article/us-usa-trump-drugpricing-idUSKBN14V24J

[5] http://thehill.com/policy/healthcare/321706-trump-to-congress-we-must-bring-down-drug-prices-immediately

[6] http://kff.org/health-costs/poll-finding/kaiser-health-tracking-poll-october-2016/

President Trump could take decisive action to address the problem of high drug prices in this instance by instructing the government to use its authority in this case under the existing Bayh Dole law.

Review of the Xtandi Petition Should Be Undertaken By An Impartial Office

If the government does proceed in reevaluating the Xtandi request, we ask that the Administration place this decision in the hands of a neutral party who does not have an established and documented predisposition against the use of government rights under Bayh Dole. It is clear from numerous statements by NIH officials, including Dr. Mark Rohrbaugh, a Special Advisor for Technology Transfer and the former head of the NIH's Office of Technology Transfer, and Director Francis Collins, that the decision on this issue should not rest with them. In December 2016, Mr. Rohrbaugh stated on several occasions that "it is not our mission to control drug prices,"[7] and that, "N.I.H. has made it clear that its job is not to decide prices of drugs, period."[8]

Similarly, Director Collins responded to questions by Senator Durbin at a hearing of the Senate Labor-HHS appropriations subcommittee on April 7, 2016 by stating that he did not believe that march-in rights under the Bayh Dole Act were intended to address problems of price but rather to address problems of access, and that he was concerned "about the negatives that may flow forward, if we use march-in rights in a very broad way about drug pricing."[9] To this, Senator Durbin responded that problems of access go beyond physical accessibility, saying, "if a drug is overpriced, it is not accessable."

Conclusion

KEI and UACT believe, along with many others, that this case continues to have merit and tremendous significance in the urgent fight against out-of-control drug prices. We believe that the Obama Administration made a mistake in not acting. And, we believe that the Trump Administration has an opportunity to rectify that mistake, and to take bold action here for the benefit of patients, consumers, and taxpayers.

We request a meeting to discuss this matter in further detail.

Sincerely,

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[7] https://www.buzzfeed.com/danvergano/nih-drug-giveaway

[8] https://www.nytimes.com/2016/12/19/health/harnessing-the-us-taxpayer-to-fight-cancer-and-make-profits.html?_r=0

[9] Video of this exchange is available here: https://www.youtube.com/watch?v=wpo5sOQV9HY

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KEI
KNOWLEDGE ECOLOGY INTERNATIONAL

UACT
UNION FOR AFFORDABLE CANCER TREATMENT

January 14, 2016

The Honorable Sylvia Mary Mathews Burwell
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Dear Secretaries Burwell and Carter and Director Collins:

Introduction

Knowledge Ecology International is a non-profit organization with offices in Washington, DC and Geneva, Switzerland. The Union for Affordable Cancer Treatment (UACT) is a non-profit cancer patient group. More about each group is available on their respective web pages: http://keionline.org and http://cancerunion.org.

This letter is a request that the U.S. federal government use its rights in patents for the prostate cancer drug (enzalutamide), marketed under the brand name of Xtandi by Japan-based Astellas

Pharma. This is a product that has an average wholesale price (AWP) of $129,269 per year,[1] and which is far more expensive in the United States than in other countries.

Specifically, we ask the Department of Health and Human Services (DHHS), National Institutes of Health (NIH), and/or the Department of Defense (DoD) to use its royalty-free rights in the relevant patents, or to grant this request for march-in rights. The relevant patents include, but are not limited to, the three patents listed in the FDA Orange Book for Xtandi (7709517, 8183274, and 9126941), all of which were granted to the Regents of the University of California, a public institution. All three inventions were made with the support of the United States government under National Institutes of Health SPORE grant number 5 P50 CA092131 and Department of Defense (Army) grant number W81XWH-04-1-0129.

The statutory basis for the request includes 35 U.S.C. § 202(c)(4), for the royalty-free rights in the patents, and 35 U.S.C. § 203(a)(1-3), noting that the term "practical application" of an invention in 35 U.S.C. § 203(a)(1) is defined by 35 U.S.C. § 201(f) to require that the benefits of an invention are "available to the public on reasonable terms." It is our contention that the pricing of Xtandi is excessive and discriminatory as regards U.S. citizens.

Xtandi is an expensive drug everywhere, indeed so expensive that access is extremely limited in many countries. But, based upon our research, the prices in the United States are far higher than any other country in the world, despite the fact that the critical research benefited from U.S. taxpayer funded grants from the NIH and DoD.

More generally, we ask the U.S. federal government to adopt the policy that the federal government will use its royalty free rights, or grant licenses under federal march-in rights, when prices in the United States are excessive, and/or higher than they are in high income foreign countries, and to apply that policy in this case for patents on enzalutamide.

Such an approach would be in accord with the policy and objective of the Bayh-Dole Act as stated in 35 U.S.C. § 200, to "protect the public against nonuse ***and*** the unreasonable use of inventions…" [emphasis added].

The analysis in this document includes the following topics and tables.

1. Prices for Xtandi are much higher in the United States than in other high income countries,
2. The high prices for Xtandi create hardships on U.S. patients,
3. The cost of Xtandi to Medicare,
4. Astellas and Medivation projections of Xtandi sales,
5. The role of the U.S. government in funding research on Xtandi,
6. Enzalutamide is an important cancer drug,

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[1] $88.48 per 40 mg unit, four times a day, 365.25 days per year.

7. The University of California at Los Angeles (UCLA) interest in the patents,
8. Orange Book patent claims for Xtandi,
9. Non-patent exclusivity,
10. Generic supply,
11. Xtandi R&D investments through the 2012 approval for the lead indication,
12. Clinical trials on enzalutamide, including trials subsequent to 2012 NDA,
13. Licensing terms, including reasonable royalty,
14. Funding of research to further develop enzalutamide,
15. Standard for determining the Xtandi prices are unreasonable.
16. Conclusion

Tables:

Table 1.1: Prices for Xtandi 40mg capsule/tabs, in the United States and 13 high income countries.
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Table 8.1: Xtandi Patents
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Table 12.1: Number of trials funded by Industry, NIH, other "U.S. Fed" and "Other," as reported in ClinicalTrials.Gov, January 6, 2016.
Table 12.2: Number of trials funded by Astellas and/or Medivation, as reported in ClinicalTrials.Gov, January 6, 2016.
Table 15.1: US Average Wholesale Price, relative to prices in reference countries

1. Prices for Xtandi are much higher in the United States than in other high income countries.

Xtandi is sold in 40 mg capsules or tablets, and is prescribed for daily use for as long as the drug continues to be effective and tolerated. The typical dose of Xtandi for the treatment of prostate cancer is 4 x 40 mg per day.

The U.S. average wholesale price (AWP), according to *Redbook* data published April 2015, was $88.48 per 40 milligram capsule, which amounts to $353.92 per day, or $129,269.28 per year (365.25 day year). The average price for Medicare in 2014 was $69.41 per capsule,[2] or $101,408.01 for a full year's treatment.

Astellas Pharma, a Japanese-owned drug company, is exploiting the weak response of the United States to excessive pricing of drugs, and is charging U.S. consumers and third-party payers roughly two to four times as much as the prices in other high income countries. For example, in Norway, a country with a per capita income of $103,630 in 2014, the price is $32.43 per 40 mg capsule, just 47 percent of the US Medicare price, and 39 percent of the Redbook AWP for the U.S. private sector.

In Australia, the price is $23.46 per capsule, roughly one third of the U.S. Medicare price. In Quebec, Canada, the price is $20.12 per capsule, just 29 percent of the U.S. Medicare price, and 24 percent of the U.S. AWP.

Astellas Pharma, the company that holds the rights to market Xtandi, is a member of the Japan-based Mitsubishi UFJ Financial Group (MUFJ) keiretsu. Note that in Japan, the price per 40 mg unit of this UCLA-invented drug is $26.37, less than one-third of the U.S. AWP.

In our opinion, it is unreasonable, and indeed outrageous, that prices are higher in the United States than in foreign countries, for a drug invented at UCLA using federal government grants.

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[2] See Centers for Medicare and Medicaid Services Medicare Drug Spending Dashboard, available at: https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Dashboard/Medicare-Drug-Spending/Drug_Spending_Dashboard.html

Table 1.1: Prices for Xtandi 40mg capsule/tabs, in the United States and 13 high income countries.

Country	Price per unit, national currency		EX Rate (Jan. 6, 2016)	Price per unit, USD	Percent of 2015 AWP	2014, GNI Per Capita, Atlas Method, USD
USA, April 2015 AWP	88.48	USD	1	$88.48	100%	$55,200
USA, 2014 Medicare	69.41	USD	1	$69.41	78%	$55,200
Australia	33.04	AUD	0.71	$23.46	27%	$64,540
Belgium	29.15	EUR	1.08	$31.48	36%	$47,260
Canada, Quebec	28.35	CAN	0.71	$20.12	23%	$51,630
France	24.75	EUR	1.08	$26.73	30%	$42,960
Germany, public insurance	34.19	EUR	1.08	$36.93	42%	$47,640
Italy, procurement price	24.08	EUR	1.08	$26.01	29%	$34,270
Japan	3,138.80	Yen	0.0084	$26.37	30%	$42,000
The Netherlands	29.15	EUR	1.08	$31.48	36%	$51,890
Norway	294.78	NOK	0.11	$32.43	37%	$103,630
Spain	29.98	EUR	1.08	$32.38	37%	$29,440
Sweden	224.705	SEK	.12	$26.96	30%	$61,610
Switzerland	35.82	CHF	0.99	$35.46	40%	$88,120*
UK	24.42	GBP	1.46	$35.65	40%	$43,430

*Only 2013 was available for Switzerland.

2. The high prices for Xtandi create hardships on U.S. patients.

Recent clinical studies indicate that treatment delays may be harmful to patients. While the drug is relatively new, clinicians are now recommending that doctors prescribe Xtandi before prescribing other drugs that target the same androgen axis, to prevent the development of drug resistance.

Since 2014, the FDA has expanded the use of Xtandi to first line treatment for metastatic castration-resistant prostate cancer (mCRPC) based on the phase III PREVAIL clinical trial. Currently Xtandi (FDA approved, 2012), Zytiga (FDA approved, 2011), and Taxotere (FDA approved, 2004) are the top three prescribed drugs in first line metastatic CRPC treatment.[3] However, using Taxotere before Xtandi has been shown to decrease the effectiveness of Xtandi by a median overall survival of 15.8 months.[4] Zytiga and Xtandi are both oral therapeutics that target the androgen signaling axis, and although prospective head-to-head comparison clinical trials are still ongoing, retrospective analysis data have indicated that there is a clear clinical cross-resistance between the two drugs.[5] In fact, in a study conducted by Schrader *et al.*, it was reported that 48.6% of patients who previously took Zytiga and Taxotere were completely resistant to Xtandi.[6] Based on the susceptibilities of individual patients, oncologists may want to prescribe Xtandi over Zytiga for its toxicity profile or to patients who cannot tolerate low-dose steroids.[6] If insurance companies were to restrict the use of Xtandi in favor of Zytiga or Taxotere, it would likely prove detrimental to the survival of those patients.

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[3] Flaig TW *et al.* Treatment evolution for metastatic castration-resistant prostate cancer with recent introduction of novel agents: retrospective analysis of real-world data.Cancer Med. 2015 Dec 29.

As a direct result of the high price charged by Astellas, U.S. insurance companies and other third party payers have predictably restricted access to Xtandi. Insurers discourage prescribers by requiring restrictive prior authorizations that prevent use of Xtandi before a patient has failed other treatments. UnitedHealthcare, for example, noted in a memorandum that "Supply limits and/or Step Therapy may be in place."[7]

Table 2.1 shows information from insurance formularies from across the United States, including whether prior authorization is required and what tier the insurer has placed the drug on in their formulary. Higher tiers generally indicate higher copays and restricted access, and insurers generally use 3- or 5-tier systems. (See the next section for a discussion of Medicare spending on Xtandi.)

Table 2.1: Prior authorization requirements and formulary tiers for seven insurers providing reimbursements for Xtandi/enzalutamide.

Payer	Formulary	Tier	Prior Authorization
Rocky Mountain Health Plans	Good Health Formulary[8]	3	Yes
Kaiser Permanente	Exchange Formulary[9]	4	No
Aetna	Three Tier Open Individual Formulary[10]	3	Yes: step therapy
Cigna	Prescription Drug List[11]	5	Yes

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[4] Crawford ED *et al.* Treating Patients with Metastatic Castration Resistant Prostate Cancer: A Comprehensive Review of Available Therapies. J Urol. 2015 Dec;194(6):1537-47.

[5] Zhang T. *et al.* Enzalutamide versus abiraterone acetate for the treatment of men with metastatic castration-resistantprostate cancer. Expert Opin Pharmacother. 2015 Mar;16(4):473-85.

[6] Schrader AJ *et al.* Enzalutamide in castration-resistant prostate cancer patients progressing after docetaxel and abiraterone. Eur Urol. 2014 Jan;65(1):30-6.

[7] https://goo.gl/PFtBkf

[8] http://www.rmhp.org/docs/default-source/resources/good_health_formulary.pdf?sfvrsn=10

[9] https://healthy.kaiserpermanente.org/static/health/pdfs/formulary/mid/mid_exchange_formulary.pdf

[10] https://goo.gl/Z31uvf

[11] http://www.cigna.com/individuals-families/prescription-drug-list?consumerID=cigna&indicator=IFP

BlueCross BlueShield	Federal Employee Program[12]	4	Yes
Montana Health CO-OP	2015 CoventryOne Prescription Drug List[13]	4	Yes
Anthem BlueCross	Select Drug List 4-Tier Formulary[14]	4	Yes

There is also a racial disparity in the incidence, mortality, and treatment of prostate cancer. NIH and DoD should be concerned that the high price of Xtandi may be contributing to systemic racial discrimination in medical care in the United States. Data collected by the Centers for Disease Control shows that African American men have higher incidence and mortality rates than all other populations. Around two times more African American men have prostate cancer than white men (graph 2.1), and around 2.5 times more African American men die from the disease compared to white men (graph 2.2).[15] In addition, African American men are more likely to have a more aggressive form of prostate cancer. Researchers believe that this racial disparity is the result of sociobiological factors that affect people of African descent.

Beyond sociobiological effects on incidence, mortality, and severity of prostate cancer, African American men face systemic discrimination that affects their access to and quality of treatment. One recent study has found that African-American men on Medicare being treated for nonmetastatic prostate cancer experienced treatment delays, and had more postoperative emergency room visits and readmissions compared to white men.[16] "This might be a form of institutional discrimination based on socioeconomic status resulting in racially disparate outcomes," wrote Dr. Otis Brawley, chief medical officer of the American Cancer Society, commenting on that study.[17]

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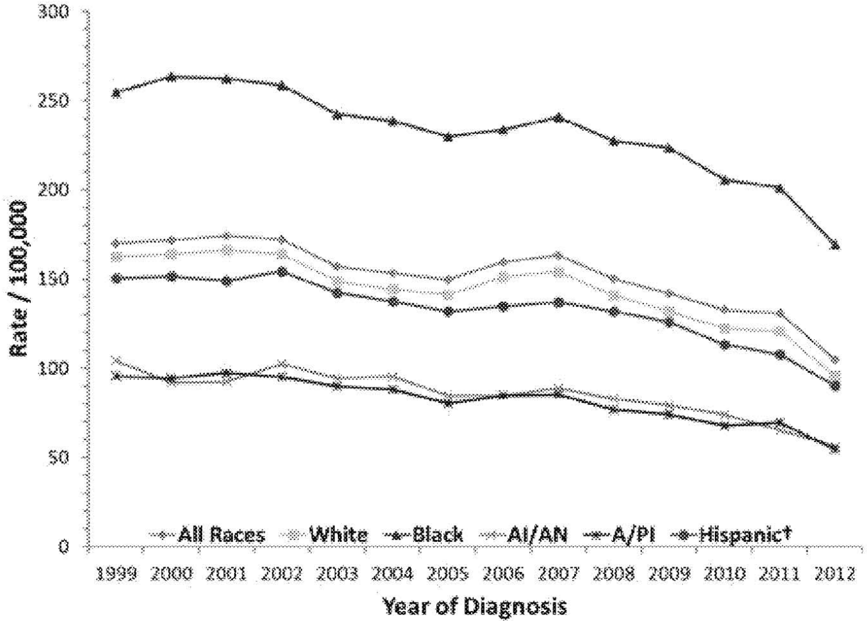
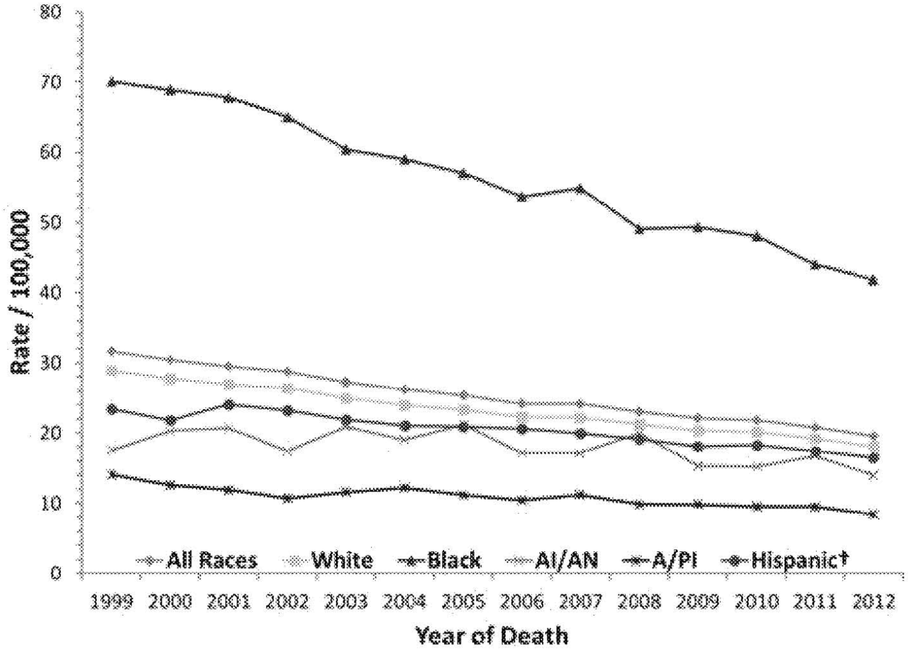
[12] https://media.fepblue.org/-/media/PDFs/Brochures/FEP_AbbreviatedFormulary_100715.pdf
[13] http://www.mhc.coop/wp-content/uploads/docs/MHC-Covered-Drugs.pdf
[14] https://fm.formularynavigator.com/MemberPages/pdf/2016CASelectHIX_7006_Full_1576.pdf
[15] See CDC, "Prostate Cancer Rates by Race and Ethnicity," available at http://www.cdc.gov/cancer/prostate/statistics/race.htm.
[16] Schmid M et al. Racial differences in the surgical care of Medicare beneficiaries with localized prostate cancer. JAMA Onc. 2015 Oct. doi:10.1001/jamaoncol.2015.3384
[17] Brawley OW. The meaning of race in prostate cancer treatment. JAMA Onc. 2015 Oct. doi:10.1001/jamaoncol.2015.3615

Graph 2.1: "Prostate Cancer Incidence Rates by Race and Ethnicity, U.S., 1999–2012"[18]



Graph 2.2: "Prostate Cancer Death Rates by Race and Ethnicity, U.S., 1999–2012"[19]



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[18] See CDC, "Prostate Cancer Rates by Race and Ethnicity," available at http://www.cdc.gov/cancer/prostate/statistics/race.htm, which contains additional notes on the data/methodologies used to create graphs 1 and 2 in this letter.

[19] See CDC, "Prostate Cancer Rates by Race and Ethnicity," available at http://www.cdc.gov/cancer/prostate/statistics/race.htm.

Veterans who served in Vietnam and the Korean demilitarized zone, who may have been exposed to Agent Orange, are also at higher risk for more aggressive forms of prostate cancer, according to a study conducted by the Department of Veterans Affairs and Oregon Health and Science University.[20]

3. The cost of Xtandi to Medicare.

According to the Centers for Medicare and Medicaid Services, total Medicare spending on Xtandi grew dramatically from under $35 million in 2012 to nearly $447 million in 2014. The increase in outlays from 2013 to 2014 was 93 percent. Part of that growth was due to a 9 percent price increase from 2012 to 2014, a period in which the Consumer Price Index (CPI) grew a mere 3 percent. There was also a steep increase in the number of patients, from 2,143 in 2012, to 7,329 in 2013, and 11,800 in 2014.

Table 3.1: Xtandi/Enzalutamide/Medicare Part D, 2012 to 2014

Year	Total Spending	Beneficiary Cost Share	Beneficiary Count	Total Annual Spending Per User	Avg Cost Per Unit	Claim Count
2012	$34,898,755.93	$2,359,870.77	2,143	$16,285.00	$63.72	4,519
2013	$231,503,731.19	$13,276,790.11	7,329	$31,587.36	$64.85	29,572
2014	$447,311,084.46	$24,567,059.52	11,800	$37,907.72	$69.41	53,980

For prostate cancer, the average age at diagnosis is 66 years. At present, approximately 14 percent of the population is 65 or over, but in five years this will increase to 16 percent, and by 2030 is expected to exceed 19 percent. As the population continues to age, we can reasonably predict that Medicare expenditures on Xtandi will continue to climb.

4. Astellas and Medivation projections of Xtandi sales.

According to the Astellas 2015 annual report,[21] the United States market will represent 61.16 percent of all global sales of Xtandi, for the fiscal year ending March 31, 2016. Note that in the U.S., sales of Xtandi increased 77 percent from FY2013 (April 1, 2013 to March 31, 2014) to FY2014 (April 1, 2014 to March 31, 2015), and are projected to increase 51 percent from FY2014 to FY2015. This is a steep increase in use for a costly drug.

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[20] Ansbaugh N et al. Agent Orange as a risk factor for high-grade prostate cancer. Cancer. 2013 Jul; 119(13):2399-2404. Available at http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4090241/.

[21] Astellas Annual Report 2015, available at https://www.astellas.com/en/ir/library/pdf/2015AR_en_1007-2.pdf.

Table 4.1: Actual and projected Xtandi sales, FY2013 to FY2015[22]

Country/Region	FY2013	FY2014	FY2015 (projected)
Japan		$125,147,037	$193,179,990
U.S.	$441,000,000	$779,000,000	$1,180,000,000
Percent Change in Sales, U.S.		77%	51%
Other Americas	$8,000,000	$24,000,000	$35,000,000
Europe, Middle East, and Africa	$75,255,950	$259,095,485	$505,289,950
Asia/Oceania		$5,039,478	$15,958,347
Global	$524,255,950	$1,192,282,001	$1,929,428,288
Percent U.S. Sales to Global	84%	65%	61%

Astellas developed Xtandi in collaboration with Medivation. The Medivation 2015 SEC 10-K filing reports actual Xtandi sales in the United States for calendar years 2012 to 2014.

Medicare's share of sales have increased sharply since 2012. In 2014 they accounted for 66 percent of Xtandi's overall U.S. sales, and 42 percent of global sales. The United States is the largest spender on Xtandi, and most of that money is coming from taxpayers and the insurance payments of aging Americans.

Table 4.2: Actual Xtandi sales, U.S., 2012 to 2014[23]

Calendar Year	**2012**	**2013**	**2014**
Xtandi U.S. Sales	$71,504,000	$392,415,000	$679,805,000
Percent Change in U.S. Sales		449%[24]	73%
Xtandi Non-U.S. Sales		$52,800,000[25]	$381,100,000
Medicare Total Spending	$34,898,755.93	$231,503,731.19	$447,311,084.46
Medicare Share of U.S. Sales	49%	59%	66%
Medicare Share of Global Sales	49%	52%	42%

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[22] Astellas defines its fiscal year as April 1 to March 31, beginning in the year indicated. Monetary amounts were converted to USD from regional currencies, as necessary.

[23] Medivation 2015 Form 10-K, available at http://files.shareholder.com/downloads/MDV/1291225255x0xS1193125-15-62576/1011835/filing.pdf.

[24] Note: Xtandi was approved on August 12, 2012, which accounts for low sales.

[25] Note: Xtandi was first approved outside the U.S. in June 2013, which accounts for low sales.

5. The role of the U.S. government in funding research on Xtandi.

As noted above, all three patents in the Orange Book for Xtandi disclose the fact that the inventions were made with the support of the United States government under National Institutes of Health SPORE grant number 5 P50 CA092131 and Department of Defense (Army) grant number W81XWH-04-1-0129.

In addition to the grants listed in these three patents, the development of this drug benefited from additional research subsidies from the federal government and charitable foundations, including grants for clinical testing of the drug. For example, a 2009 paper in *Science* reporting on the development of MDV3100 (the development name for enzalutamide)[26] acknowledged funding from the Prostate Cancer Foundation, the National Cancer Institute, the DOD PC051382 Prostate Cancer Research Program Clinical Consortium Award, and support from the Charles H. Revson Foundation. Likewise, a 2010 paper in *the Lancet* reporting on a critical Phase 1-2 trial acknowledges the financial support of Medivation, but also the Prostate Cancer Foundation, National Cancer Institute, the Howard Hughes Medical Institute, Doris Duke Charitable Foundation, and Department of Defense Prostate Cancer Clinical Trials Consortium. [27]

6. Enzalutamide is an important cancer drug.

In the United States today there are nearly 3 million men suffering from prostate cancer, with over 220,000 new cases in 2015 alone, and 27,540 deaths. It is the third most common form of cancer in the U.S.

When patients are treated early and tumors are localized, the prognosis is often favorable. However, some patients will relapse, leading in nearly all cases to castration resistant prostate cancer (CRPC). At the CRPC stage, the disease is no longer responsive to androgen deprivation therapy (ADT), thus limiting the available treatment options with a greater disease burden. Access to Xtandi/enzalutamide, a non-steroidal second generation androgen receptor agonist, becomes critical to extending the life of the patient, and allowing patients to live an improved quality of life.

There are currently six treatments being used to treat CRPC. Xtandi/enzalutamide has several advantages over the other treatments. Four of the treatments are invasive and require I.V. administration, leukapheresis, or the use of radiopharmaceuticals. Xtandi/enzalutamide and Zytiga are the only daily oral tablets. However Xtandi/enzalutamide's pill burden is lighter since it does not need to be taken in combination with prednisone. As such, Xtandi/enzalutamide is well tolerated and has more favorable toxicity profile.

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[26] Tran C *et al.* Development of a second-generation antiandrogen for treatment of advanced prostate cancer. Science. 2009. May. 8;324(5928):787-90.

[27] Scher HI *et al.* Antitumour activity of MDV3100 in castration-resistant prostate cancer: a phase 1-2 study, Lancet. 2010 Apr 24;375(9724):1437-46. doi: 10.1016/S0140-6736(10)60172-9.

Quality of life was also more frequently improved and median time to deterioration was significantly longer with Xtandi/enzalutamide compared to placebo, as reported by patients in functional assessment questionnaires administered during clinical trials.[28]

With recent and ongoing clinical trials reporting better prostate cancer control when Xtandi/enzalutamide is used in chemotherapy naive CRPC cases or in combination with other agents, it is expected that this drug will soon be prescribed to wider subset of patients.[29,30,31] In fact experts say that in the next 3 years all CRPC will progress to Xtandi or Zytiga.[32]

Xtandi/enzalutamide is also being tested for other types of cancer, including clinical trials for breast cancer (triple negative[33], her2+[34]), hepatocellular carcinoma[35], bladder cancer[36], ovarian or fallopian tube cancer,[37] pancreatic cancer[38] and Mantle Cell Lymphoma[39].

7. The University of California at Los Angeles (UCLA) interest in the patents

According to the Medivation's 2014 10-K report to the Securities and Exchange Commission (SEC), the University of California at Los Angeles (UCLA) licensed the patents for the drug to Medivation in exchange for an annual payment of $2.8 million, a 4 percent royalty on global net sales of the drug, and in addition a 10 percent share of Medivation's sublicensing income derived from the Astellas Collaboration Agreement.[40] The Astellas Collaboration Agreement has separate terms for U.S. and non-U.S. sales, as described below:

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[28] Rodriguez-Vida A *et al.* Enzalutamide for the treatment of metastatic castration-resistant prostate cancer.Drug Des Devel Ther. 2015 Jun 29;9

[29] Scher HI *et al.* Increased survival with enzalutamide in prostate cancer after chemotherapy. N Engl J Med. 2012 Sep.

[30] Loriot Y *et al.* Effect of enzalutamide on health-related quality of life, pain, and skeletal-related events in asymptomatic and minimally symptomatic, chemotherapy-naive patients with metastatic castration-resistant prostate cancer (PREVAIL): results from a randomised, phase 3 trial. Lancet Oncol. 2015 May.

[31] STRIDE results presented at 2015 American Society of Clinical Oncology annual meeting, Clinicaltirals.gov:NCT01981122.

[32] Zhang T. *et al.* Enzalutamide versus abiraterone acetate for the treatment of men with metastatic castration-resistantprostate cancer. Expert Opin Pharmacother. 2015 Mar;16(4):473-85.

[33] NCT01889238.

[34] NCT02091960.

[35] NCT02528643, NCT02642913. Hepatocellular carcinoma (HCC, also called malignant hepatoma) is the most common type of liver cancer, often secondary to a viral hepatitis infection (hepatitis B or C) or cirrhosis.

[36] NCT02605863, NCT02300610.

[37] NCT02300610.

[38] NCT02138383.

[39] NCT02489123. Mantle cell lymphoma (MCL) is a rare, B-cell NHL that most often affects men over the age of 60.

> **Medivation 2014 10-K**
>
> p.121:
>
> **(c) License Agreement with UCLA**
>
> Under an August 2005 license agreement with UCLA, the Company's subsidiary Medivation Prostate Therapeutics, Inc. holds an exclusive worldwide license under several UCLA patents and patent applications covering XTANDI and related compounds. Under the Astellas Collaboration Agreement, the Company granted Astellas a sublicense under the patent rights licensed to it by UCLA.
>
> The Company is required to pay UCLA (a) an annual maintenance fee, (b) $2.8 million in aggregate milestone payments upon achievement of certain development and regulatory milestone events with respect to XTANDI (all of which has been paid as of December 31, 2014), (c) ten percent of all Sublicensing Income, as defined in the agreement, which the Company earns under the Astellas Collaboration Agreement, and (d) a four percent royalty on global net sales of XTANDI, as defined.
>
> --
> p.104-105
>
> **(c) Collaboration Revenue**
>
> Collaboration revenue consists of three components: (a) collaboration revenue related to U.S. XTANDI sales; (b) collaboration revenue related to ex-U.S. XTANDI sales; and (c) collaboration revenue related to upfront and milestone payments.
>
> [...]
>
> ***Collaboration Revenue Related to U.S. XTANDI Sales***
>
> Under the Astellas Collaboration Agreement, Astellas records all U.S. XTANDI sales. The Company and Astellas share equally all pre-tax profits and losses from U.S. XTANDI sales. Subject to certain exceptions, the Company and Astellas also share equally all XTANDI development and commercialization costs attributable to the U.S. market, including cost of goods sold and the royalty on net sales payable to UCLA under the Company's license agreement with UCLA. The primary exceptions to the equal cost sharing are that each party is responsible for its own commercial FTE costs and that development costs supporting marketing approvals in both the United States and either Europe or Japan are borne one-third by the Company and two-thirds by Astellas. The Company recognizes collaboration revenue related to U.S. XTANDI sales in the period in

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[40] UNITED STATES SECURITIES AND EXCHANGE COMMISSION, Form 10-K, For the Fiscal Year Ended December 31, 2014, http://www.sec.gov/Archives/edgar/data/1011835/000119312515062576/d850483d10k.htm

> which such sales occur. Collaboration revenue related to U.S. XTANDI sales consists of the Company's share of pre-tax profits and losses from U.S. sales, plus reimbursement of the Company's share of reimbursable U.S. development and commercialization costs. The Company's collaboration revenue related to U.S. XTANDI sales in any given period is equal to 50% of U.S. XTANDI net sales as reported by Astellas for the applicable period.
>
> [...]
>
> ***Collaboration Revenue Related to Ex-U.S. XTANDI Sales***
>
> Under the Astellas Collaboration Agreement, Astellas records all ex-U.S. XTANDI sales. Astellas is responsible for all development and commercialization costs for XTANDI outside the United States, including cost of goods sold and the royalty on net sales payable to UCLA under the Company's license agreement with UCLA, and pays the Company a tiered royalty ranging from the low teens to the low twenties on net ex-U.S. XTANDI sales. The Company recognizes collaboration revenue related to ex-U.S. XTANDI sales in the period in which such sales occur. Collaboration revenue related to ex-U.S. XTANDI sales consists of royalties from Astellas on those sales.
>
> [...]

Medivation came to acquire rights to Xtandi from UCLA through an agreement initiated by Dr. Charles L. Sawyers and Dr. Michael E. Jung, researchers at UCLA working on prostate cancer screening techniques and treatments. Dr. Sawyers is an oncologist who currently runs a lab at Memorial Sloan Kettering Cancer Center and serves on the Board of Directors for Novartis.[41] He was a key participant in the development of Gleevec and Sprycel, and is a recipient of the Lasker Award. Dr. Michael E. Jung is a Distinguished Professor of Chemistry at UCLA, where he runs a lab that conducts research on chemicals related to the treatment of cancer.

Dr. Sawyers approached Medivation through its founder, Dr. David Hung, a former colleague at the University of California, San Francisco. They settled on an agreement that required Dr. Sawyers and Dr. Jung to disclose all molecules related to their prostate cancer research that benefitted from Medivation funding. Dr. Sawyers served on Medivation's Scientific Advisory Board, as did Dr. Jung, receiving $20,000 and $400,000 worth of stocks, respectively.

In addition, Dr. Sawyers and Dr. Jung used the fruits of their research to found their own pharmaceutical firm, Aragon Pharmaceuticals, which they used as a vehicle to develop a drug with a very similar chemical structure to Xtandi. Medivation sued the doctors, Aragon, and UCLA, over the development of that drug.[42] According to SEC filings, Medivation and UCLA are now engaged in separate litigation over licensing payments on Xtandi.[43]

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[41] More on Dr. Sawyers is available here: http://www.bloomberg.com/research/stocks/private/person.asp?personId=12631592&privcapId=25460204.

[42] For an amended complaint, filed February 9, 2012, see here: https://goo.gl/p3lpnm.

[43] Medivation 2015 10-K SEC filing, available here: http://files.shareholder.com/downloads/MDV/1291225255x0xS1193125-15-62576/1011835/filing.pdf.

8. Orange Book patent claims for Xtandi

As noted above, Astellas has listed three patents in the FDA Orange book for Xtandi sales. These include US patent number 7709517, for both a drug substance and drug product claim, and two additional patents, US patent numbers 8183274 and 9126941.

Table 8.1: Xtandi Patents

Patent Number	**7,709,517**	**8,183,274**	**9,126,941**
Title:	Diarylhydantoin compounds	Treatment of hyperproliferative disorders with diarylhydantoin	Treatment of hyperproliferative disorders with diarylhydantoin compounds
Publication date	May 4, 2010	May 22, 2012	Sep 8, 2015
Filing date	May 15, 2006	Feb 18, 2010	Apr 17, 2012
Priority Date	May 13, 2005	May 13, 2005	May 13, 2005
Inventors	Charles L. Sawyers, Michael E. Jung, Charlie D. Chen, Samedy Ouk, Derek Welsbie, Chris Tran, John Wongvipat, Dongwon Yoo	Charles L. Sawyers, Michael E. Jung, Charlie D. Chen, Samedy Ouk, Chris Tran, John Wongvipat	Charles L. Sawyers, Michael E. Jung, Charlie D. Chen, Samedy Ouk, Chris Tran, John Wongvipat
Original Assignee	The Regents Of The University Of California	The Regents Of The University Of California	The Regents Of The University Of California
Expiration date	Aug 13, 2027	May 15, 2026	May 15, 2026
FDA substance claim	Yes		
FDA product claim	Yes		
FDA use claim code		U - 1281; The treatment of patients with metastatic castration-resistant prostate cancer (CRPC) who have previously	U - 1588, The treatment of patients with metastatic castration-resistant prostate cancer (CRPC).

		received docetaxel. U - 1588, The treatment of patients with metastatic castration-resistant prostate cancer (CRPC).	
Disclosure of US rights in the patent	This invention was made with United States Government support under National Institutes of Health SPORE grant number 5 P50 CA092131 and Department of Defense (Army) grant number W81XWH-04-1-0129. The Government has certain rights in the invention.	This invention was made with United States Government support under National Institutes of Health SPORE grant number 5 P50 CA092131 and Department of Defense (Army) grant number W81XWH-04-1-0129. The Government has certain rights in the invention.	This invention was made with Government support under Grant No. W81XWH-04-1-0129 awarded by the United States Army, Medical Research and Materiel Command; Grant No. CA092131 awarded by the National Institutes of Health. The Government has certain rights in this invention.

9. Non-patent exclusivity.

The FDA Orange Book lists two grants of non-patent exclusivity to Astellas for enzalutamide, both expiring in 2017. One was granted for enzalutamide as a new chemical entity, expiring August 31, 2017; the second was granted under code I-693 for “treatment of patients with metastatic castration-resistant prostate cancer (CRPC)”, expiring September 10, 2017. These dates are sufficiently close that they should not be used to excuse non-action on this request, particularly since it may take several months for a generic supplier to prepare data for an Abbreviated New Drug Application (ANDA).

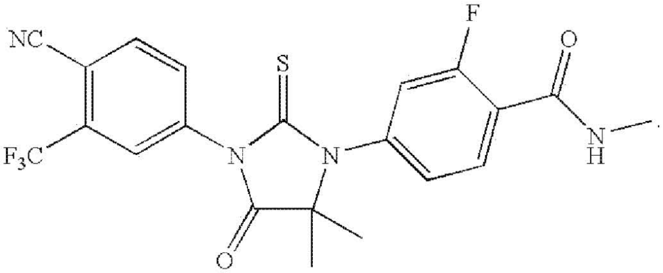
10. Generic supply

Enzalutamide is a small molecule drug that does not have a complex structure.

Enzalutamide is a synthetic, non-steroidal pure antiandrogen, originally named MDV3100, which has the formula $C_{21}H_{16}F_4N_4O_2S$, a molar mass of 464.44 g/mol and a chemical name of 4-(3-(4-Cyano-3-(trifluoromethyl)phenyl)-5,5-dimethyl-4-oxo-2-thioxoimidazolidin-1-yl)-2-fluoro-N-methylbenzamide. The chemical structure, illustrated in Figure 1, includes a thiohydantoin and two benzene groups.

Figure 10.1: Structure of MDV3100 (CAS number: 915087-33-1)

[RD162']



Petitioners have excellent relations with several generic drug manufacturers, and do not anticipate difficulties obtaining the necessary FDA approvals for generic versions of enzalutamide, once the federal government provides access to the patents, either by using the royalty-free right in the patents or granting this march-in request.

Note that the 2015 U.S. AWP for Xtandi of $88.48 per 40 mg capsule is equivalent to $2,212 per gram of active pharmaceutical ingredient.

Generic products with similar complexity for manufacturing can be obtained for under $10 per gram of API, retail,[44] and considerably less in bulk.

11. Xtandi R&D investments through the 2012 approval for the lead indication

Xtandi was approved as a treatment for prostate cancer in August 31, 2012, as a priority drug under the FDA Priority Review program. The application was by Astellas, and was approved by the FDA as NDA 203415.

The application for the NDA was supported by evidence from four clinical trials, including one Phase 1 trial with 140 patients enrolled, one Phase 1/2 trial with 27 patients enrolled, one Phase 2 trial with 60 patients enrolled, and one Phase 3 trial with 1,199 patients enrolled. Total enrollment for the 4 trials was 1,426 patients.

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[44] For example, generic versions of the cancer drug imatinib.

Table 11.1: Trials Reported in FDA Medical Review for 2012 Approval for Xtandi

Study Number	NCT Number	Phase	Start- End Date	Enrolled (FDA Review)	Study Sponsor	Federal Funding
S-3100-1-01	NCT00510718	1	7/2007- 1/2010	140	Medivation	NCI, DoD[45]
CRPC-MDA-1	NCT01091103	2	2/2010- 7/2011	60	Medivation	NCI, DoD[46]
CRPC2	NCT00974311	3	9/2009- 9/2011	1199	Medivation	n/a
9785-CL-0111	NCT01284920	1/2	11/2010- 7/2012	27	Astellas Pharma	n/a

The two earliest trials (NCT00510718, NCT01091103) received subsidies from the National Cancer Institute and Department of Defense, in addition to funding from the Prostate Cancer Foundation and other non-profit institutions. After receiving favorable results from the trials subsidized by NCI and DoD, Medivation and Astellas funded two additional trails.

The size of the trials for Xtandi were typical of other cancer drugs approved from 2010 to 2014 for the lead indication as a New Molecular Entity, and much smaller than trials used to approve non-cancer drugs.

Table 11.2: Trial enrollment cited in in FDA medical reviews for lead indication of new drugs, 2010 to 2014

Average for all cancer drugs	1,316
Average for non-Cancer Drugs	4,733
Xtandi	1,426

Medivation reported their direct expenditures and cost-sharing payments from Astellas for collaboration on the development of Xtandi between 2005 and 2012, when the FDA granted Xtandi marketing approval. They defined direct costs as “clinical and preclinical study costs, cost of supplying drug substance and drug product for use in clinical and preclinical studies, contract research organization fees, and other contracted services pertaining to specific clinical and preclinical studies.”[47] The number reported excludes indirect costs, which include “administrative and support costs.”[48]

Astellas contributed to half of all direct costs for R&D conducted for U.S. drug approval, two-thirds of costs for R&D directed towards trials aimed at both U.S. and non-U.S. use of

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[45] Scher, Howard I., et al. "Antitumour activity of MDV3100 in castration-resistant prostate cancer: a phase 1–2 study." *The Lancet* 375.9724 (2010): 1437-1446.

[46] Efstathiou, Eleni, et al. "Molecular characterization of enzalutamide-treated bone metastatic castration-resistant prostate cancer." *European urology* 67.1 (2015): 53-60.

[47] Medivation 2009 10-K SEC filing, available here: http://files.shareholder.com/downloads/MDV/1291225255x0xS1193125-10-57020/1011835/filing.pdf.

[48] Ibid. Indirect costs for all drugs combined are available in Medivation SEC filings.

Xtandi, and full development costs for commercialization outside the United States. Based upon the Medivation SEC filings, R&D outlays on Xtandi were $303 million through the end of the calendar year 2012.

Table 11.3: R&D expenditures on Xtandi, 2005-2012 (in thousands of USD)

SEC 10-K Year	2005	2006	2007	2008	2009	2010	2011	2012
Medivation Direct Costs	$261	$3,021	$2,619	$8,845	$27,046	$23,454	$42,3350	$67,086
Development cost-sharing payments from Astellas					$2,784	$34,125	$44,285	$47,473
Total	$261	$3,021	$2,619	$8,845	$29,830	$57,579	$86,620	$114,559
Cumulative Total								$303,334

Medivation reported outlays of an additional $285 million in calendar years 2013 and 2014, much of that money aimed at justifying broader use of Xtandi for prostate cancer, but also on testing the drug to treat other types of cancer.

Table 11.4: R&D expenditures on Xtandi, 2013 and 2014 (in thousands of USD)

SEC 10-K Year	2013	2014
Medivation Direct Costs	$73,076	$102,669
Development cost-sharing payments from Astella	$46,594	$63,479
Total	$119,670	$166,148
Cumulative Total		$285,818

The company outlays on R&D investments were significant, although it is worth noting that the early and most risky trials were small and subsidized by the United States government.

Note that through the end of 2014, representing a little more than two years of reimbursements, Medicare spent $704 million on Xtandi. Astellas expects a sharp increase in U.S. sales in 2015 and 2016, and the company revenues also include sales from non-Medicare patients in the United States and patients outside of the United States.

12. Clinical trials on enzalutamide, including trials subsequent to 2012 NDA.

Like many cancer drugs, the initial approval of the drug for the lead indication has lead to continued research to determine the best uses of the drugs, both for prostate cancer patients and to test the benefits of using enzalutamide to treat other types of cancer.

As of January 6, 2015, there were 129 trials listed in the ClinicialTrials.Gov database.

The funding of the trials is reported under the categories Industry, U.S. Fed., NIH, and Other, as well as combinations of those categories.

- 54 of the 129 trials were reported as funded by Industry alone.
- Another 31 trials were reported as funded by Industry and some other funder.
- The NIH or other U.S. Federal agencies were reported as funders in whole or in part of 18 trials.
- The category "Other" is quite important, accounting for 29 trials funded exclusively by Other, and another 42 where "Other" is among the funders.

Many of the trials funded by "Other" refer to universities and other non-profit research organizations that receive NIH or other federal agency research grants. "Other" also refers to funding from foreign governments and charities.

Table 12.1: Number of trials funded by Industry, NIH, other "U.S. Fed" and "Other," as reported in ClinicalTrials.Gov, January 6, 2016.

Funder	Number of Trials
"Industry" only	54
Mixed including "Industry"	31
"Other" only	29
Mixed including "Other"	42
NIH only	3
Mixed including NIH or other "U.S. Fed"	16

Table 12.2: Number of trials funded by Astellas and/or Medivation, as reported in ClinicalTrials.Gov, January 6, 2016.

Funder	Number of Trials
Astellas and/or Medivation as sponsor of industry only funded trials	39
Astellas and/or Medivation as sponsor of mixed funded trials	18

Among the trials funded in whole or in part by "Industry", the majority, 57, were funded by Astellas and/or Medivation, and of those only for 39 (30 percent of the 129) were they the sole funder of the trials.

Other companies, such as Lilly, Gilead, Roche, Bayer, Sanofi, and smaller companies, were involved in funding 28 trials.

13. Licensing terms, including reasonable royalty.

We are requesting the federal government grant an open license to any generic drug manufacturer.

The federal government has no obligation to pay royalties on the patents when and if it exercises its royalty free rights in the patents.

If the government orders the licensing of the patents under the federal march-in statutes, the terms of the license, including the royalty, have to be "reasonable under the circumstances."[49]

The issue of the appropriate royalty rate can be briefed and argued when and if the federal government is inclined to exercise march-in rights on the patent.

"Under the circumstances" would include many factors, such as that the facts motivating the granting of the march-in request are related to abuses of the patent rights, including in particular charging an excessive price and discriminating against U.S. consumers.

Rights in test data

Patents are granted for inventions, but as noted above, patents are not the only intellectual property rights associated with drug development.

The FDA provides additional intellectual property rights for investments in clinical trials, including five years of exclusive rights to rely upon data supporting the registration of a new chemical entity, and three years of rights in the data to support new indications on a drug.

The five years of test data exclusivity for Xtandi as a treatment for patients with metastatic castration-resistant prostate cancer (CRPC) will expire on September 10, 2017 in the United States, and later in many other countries. For example, the term of protection for test data is up to 8 years in Japan and Canada, and 11 years in the European Union.[50] The rights in test data are designed to protect and reward investments in clinical trials, and they operate separately from patent protection. The existence of the test data rights eliminates the need to consider investments in clinical trials when considering the royalty to the patent holder, because those investments are protected by this separate intellectual property right. As regards the investments in the U.S. market, it is likely that Astellas will have earned more than $5 billion from the U.S. market alone, through September 10, 2017, the date of the most relevant test data exclusivity in the United States ends. Astellas will have also earned billions more from sales outside of the United States, where most patients reside.

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[49] 35 USC 203(a).

[50] Comparison of the Non-patent Drug Exclusivities Available in the United States, Canada, Europe and Japan. The International Economic Forum of the Americas. Serge Lapointe, Ph.D. June 14, 2012 http://forum-americas.org/sites/default/files/documents/20120614-lapointe-pres.pdf

Average industry royalty rates

According to the IRS, in 2012, the average rate of aggregate royalties (for all patents, know-how, trademarks, etc.[51]), reported on corporate income tax returns for the pharmaceutical and medicine manufacturing sector (MINOR CODE 325410) was 6.95 percent.

14. Funding of research to further develop enzalutamide.

One possible argument against any policy that lowers drug prices or shortens the term of a monopoly is that society benefits from the incentive to invest in R&D to find new uses for a drug.

It is possible to address the objective of providing sustainable sources of R&D funding without having high prices or longer monopolies.

On at least two occasions in the past involving NIH funded cancer drugs, and more recently in connection with proposals to create or extend monopolies in various drafts of the 21st Century Cures Act, there have been proposals to have mandates for funding R&D.

In one case, involving a dispute over the term of the monopoly on the cancer drug cisplatin in the early 1980s, there was a proposal that generic firms be obligated to contribute to the costs of ongoing research to determine new uses for the drug, following generic entry. This proposal, made by a generic drug company seeking to end the cisplatin monopoly, led to a compromise whereby Bristol-Myers was allowed to extend the monopoly for five more years, but only after they lowered the price of cisplatin and contributed tens of millions of dollars to independent research through non-profit institutions, at the direction of the NIH. Later, BMS proposed something similar, in an unsuccessful effort to extend data exclusivity on the cancer drug Taxol. In early drafts of the the 21st Century Cures legislation, there were proposals to associate extensions of drug monopolies with obligations to provide money to the NIH, and to make other investments in R&D.

In this case involving Xtandi, the NIH could simultaneously end the Xtandi monopoly and require any generic drug company to make contributions toward follow-on research to explore new and/or better uses of enzalutamide. Such obligations could be a condition of any use of the federal government's royalty free right in the drug, or as a condition of obtaining a march-in license.

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[51] The IRS does not provide a definition of royalties. See: https://www.irs.gov/pub/irs-tege/eotopicd89.pdf.

Note that there are benefits in having different parties participate in the testing of drugs, including those that do not have conflicts of interest as regards reporting possible negative impact of products, or allowing greater competition in designing better delivery mechanisms or new combination products. Also, in the case of Xtandi, more than half of the trials involving enzalutamide are already funded by entities other than Astellas.

15. Standard for determining that Xtandi prices are unreasonable.

In determining if the prices for Xtandi violate the statutory obligation to make products available to the public on reasonable terms and conditions, the NIH has broad discretion to consider a variety of factors, including the high price of the drug and the fact that the high price leads to restrictions on access and financial hardships on patients. However, in this case, we recommend the NIH address a narrower question, that can be answered clearly, given the robust evidence.

Do the Astellas prices for Xtandi discriminate against consumers in the United States? And, if so, the NIH should approve the March-In request, or use its royalty free rights in the patents, to prevent U.S. residents from paying more for a drug invented on federal grants than residents of other high income countries.

We have obtained prices for Xtandi in the United States and in 13 other high income countries, and this data allows the NIH to determine whether U.S. consumers are being asked to pay more for a drug invented on federal grants than Astellas charges in other high income countries.

One possible comparison to determine if the price is unreasonable is to consider the prices in other industrialized countries outside of the United States that have (1) per capita incomes of at least half that of the United States, (2) have the large economies as measured by the GDP, and (3) are members of the OECD, and to consider the U.S. price to be unreasonable, if the average wholesale price (AWP) in the U.S. is higher than the median price in the reference countries.

We propose using an odd number of countries. The 13 countries that have incomes at least 50 percent of the United States and which have the largest economies include Japan, Germany, France, the UK, Italy, Canada, Australia, Spain, the Netherlands, Switzerland, Sweden, Belgium and Norway.

We have prices for all 13 of the reference countries. None of the prices are higher than $36.93, and the April 2015 U.S. AWP was $88.48. It is not a close call: the U.S. prices are discriminatory and are unfair to U.S. residents. Note that the *highest* price of the 13 high income reference countries was less than half (42 percent) of the average wholesale price (AWP) in the United States, the median of the 13 prices reference prices we have obtained is just 36 percent of the US AWP, and the prices in Japan and Canada are 30 percent and 23 percent respectively of US AWP. As a percentage in 2014 per capita income, the U.S. prices are also far higher than for any of the 13 high income countries. In eight countries, the annual cost of Xtandi is between 47 percent and 97 percent of annual per capita income. In four countries, the annual cost of Xtandi is between 111 percent and 161 percent of per capita income. In the United States, the annual cost of Xtandi is 234 percent of 2014 per capita income.

Table 15.1: US Average Wholesale Price, relative to prices in 13 reference countries

	2014 GDP	2014 annual Per Capita Income	price per 40 mg unit	Annual price (x 4x 365.25) as percent of 2014 per capita income
United States, Average Wholesale price April 2015	$17,419,000,000,000	$55,200	$88.48	234%
Japan	$4,601,461,206,885	$42,000	$26.37	92%
Germany	$3,868,291,231,824	$47,640	$36.93	113%
France	$2,829,192,039,172	$42,960	$26.73	91%
United Kingdom	$2,988,893,283,565	$43,430	$35.65	120%
Italy	$2,141,161,325,367	$34,270	$26.01	111%
Canada	$1,785,386,649,602	$51,630	$20.12	57%
Australia	$1,454,675,479,666	$64,540	$23.46	53%
Spain	$1,381,342,101,736	$29,440	$32.38	161%
Netherlands	$879,319,321,495	$51,890	$31.48	89%
Switzerland	$701,037,135,966	$88,120*	$35.46	59%
Sweden	$571,090,480,171	$61,610	$26.96	64%
Belgium	$531,546,586,179	$47,260	$31.48	97%
Norway	$499,817,138,323	$103,630	$33.09	47%
Median, reference countries			$31.48	91%
Unweighted average, reference countries			$29.70	89%

* For Switzerland, only 2013 per capita income was available.

One defense for the high U.S. price for Xtandi would be that the product could not have been developed at a lower price. But given the significant market for this drug, the federal subsidies in both the preclinical and clinical stages, and the fact that prostate cancer is the among the three most common types of cancer,[52] that defense can be rejected entirely, and certainly going forward, given the billions of dollars in revenue already earned by Astellas.

16. Conclusion

We are requesting the federal government take steps to address the discriminatory and unfair pricing of Xtandi/enzalutamide by Astellas. U.S. residents should not have to pay two to four times as much for a cancer drug than residents of other high income countries, particularly when the drug was invented with the support of federal grants and benefited from other federal research subsidies. The average wholesale price for Xtandi was $129,269 per year in 2015, and this was more than twice as high as the price in any other high income country in our 13 country survey, and four times as high as the price in Canada. U.S. taxpayers are generous when it comes to financing research programs at the NIH, the U.S. Department of Defense, and in other federal agencies. However, we should not allow the companies that commercialize this research to discriminate and use unfair prices that impose financial hardships on U.S. residents, create access barriers for cancer patients, and make our workforce less competitive in global markets.

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[52] American Cancer Society: Cancer Facts and Figures 2015. Atlanta, Ga: American Cancer Society, 2015.

There are many areas where current U.S. laws are inadequate to address excessive or unfair prices. This is not one of them. The Bayh-Dole Act was passed with the promise that the federal March-In rights or the federal government royalty-free rights in patents would be available to protect the public from the unreasonable use of patented inventions. This is such a case.

Please contact Andrew S. Goldman, counsel for Policy and Legal Affairs at KEI, about this request. He can be reached at andrew.goldman@keionline.org, or by telephone at +1.202.332.2670.

Sincerely,

James Packard Love, Andrew S. Goldman, Diane Singhroy, Zack Struver, Claire Cassedy and Elizabeth Rajasingh, on behalf of
Knowledge Ecology International
1621 Connecticut Avenue, Suite 500
Washington, DC 20009
http://keionline.org

Manon Ress, Michael Davis and Ruth Lopert, on behalf of
Union for Affordable Cancer Treatment (UACT
http://cancerunion.org

Cc:

Army research Laboratory
Domestic Technology Transfer (Patent Licensing, Cooperative R&D Agreements, Test Service Agreements) via ORTA@arl.army.mil

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John P. Holdren, via jholdren@ostp.eop.gov
Tom Kalil, via: tkalil@ostp.eop.gov

Senators Boxer, Brown, Grassley, King Leahy, McCain McCaskill Nelson Sanders, Schumer Sessions, and Wyden

Representatives Doggett, Schakowsky, Tom Price, Markwayne Mullin, the Congressional Prostate Cancer Task Force

From: Andrew S. Goldman [andrew.goldman@keionline.org]
Sent: 4/18/2017 6:43:04 PM
To: Price, Thomas (HHS/OS) [/O=NIH/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=D76b3edcd55c49e29c9361e5073a5fef-Price, Thomas E. (OS]; whs.pentagon.esd.mbx.cmd-correspondence@mail.mil
CC: Collins, Francis (NIH/OD) [E] [/O=NIH/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=Collinsfr]
Subject: Request for Reevaluation of Xtandi Bayh Dole Petition
Attachments: KEI-UACT-April_19_2017-Xtandi-Appeal.pdf; KEI-March_10_2017-3rd-Comments-Zika.pdf; Xtandi-March-In-Request-Letter-14Jan2016.pdf

Dear Secretaries Price and Mattis:

On behalf of Knowledge Ecology International and the Union for Affordable Cancer Treatment, attached please find a request that the United States Government reconsider the decision of the Obama Administration to deny our petition, initially filed in January 2016, that the government use its rights in patents under the Bayh Dole Act (35 U.S.C. §§ 200 et seq.) for the excessively-priced, blockbuster drug enzalutamide (marketed by Astellas Pharma as Xtandi).

For reference, we additionally attach two documents that we refer to in this request, including: (1) the original petition of January 14, 2016, and (2) comments filed on March 10, 2017 in a separate matter that are relevant to the analysis of the Bayh Dole language regarding "reasonable terms".

We thank you in advance for your attention to this important matter, and request a meeting to discuss in further detail.

Sincerely,

Andrew S. Goldman
Counsel, Policy and Legal Affairs
Knowledge Ecology International
andrew.goldman@keionline.org
tel.: +1.202.332.2670
www.keionline.org

From: Rodriguez, Richard (NIH/NCI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=8092CB5394E04733AC0D4D84D25F65E5-RODRIGR]
Sent: 6/21/2018 7:53:44 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]
CC: Lambertson, David (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3c95b34f709746a8a2553ce54e74ace2-lambertsond]
Subject: RE: quick question from a journalist

This looks great with just a couple of comments.

Thanks,

Richard

From: Rohrbaugh, Mark (NIH/OD) [E]
Sent: Thursday, June 21, 2018 3:44 PM
To: Lambertson, David (NIH/NCI) [E] <david.lambertson@nih.gov>
Cc: Rodriguez, Richard (NIH/NCI) [E] <richard.rodriguez@nih.gov>
Subject: RE: quick question from a journalist

How does this sound as a response to the reporter from OC. They have worked with him before and I have interviewed with him.

b5

From: Lambertson, David (NIH/NCI) [E]
Sent: Thursday, June 21, 2018 3:16 PM
To: Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>
Cc: Rodriguez, Richard (NIH/NCI) [E] <richard.rodriguez@nih.gov>
Subject: RE: quick question from a journalist

b5

Let me know if you need any other details.

David A. Lambertson, Ph.D.
Senior Technology Transfer Manager
Technology Transfer Center
National Cancer Institute/NIH
david.lambertson@nih.gov
http://ttc.nci.nih.gov/

9609 Medical Center Drive, Rm 1-E530 MSC 9702
Bethesda, MD 20892-9702 (USPS)
Rockville, MD 20850-9702 (Overnight/express mail)
Phone (Main Office): 240-276-5530
Phone (direct): b6
Fax: 240-276-5504

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From: Rohrbaugh, Mark (NIH/OD) [E]
Sent: Thursday, June 21, 2018 3:09 PM
To: Lambertson, David (NIH/NCI) [E] <david.lambertson@nih.gov>
Cc: Rodriguez, Richard (NIH/NCI) [E] <richard.rodriguez@nih.gov>
Subject: RE: quick question from a journalist

b5

From: Lambertson, David (NIH/NCI) [E]
Sent: Thursday, June 21, 2018 3:05 PM
To: Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>
Cc: Rodriguez, Richard (NIH/NCI) [E] <richard.rodriguez@nih.gov>
Subject: FW: quick question from a journalist

Hi Mark,

I also received this question from a non-KEI entity. b5

Thanks,

David A. Lambertson, Ph.D.
Senior Technology Transfer Manager
Technology Transfer Center
National Cancer Institute/NIH
david.lambertson@nih.gov
http://ttc.nci.nih.gov/

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From: Silverman, Ed [mailto:ed.silverman@statnews.com]
Sent: Thursday, June 21, 2018 11:25 AM
To: Lambertson, David (NIH/NCI) [E] <david.lambertson@nih.gov>
Subject: quick question from a journalist

Hi Dave,

My name is Ed Silverman and I run the Pharmalot blog at The Boston Globe's STAT health news site, where I track the pharmaceutical industry.

A quick question about the NIH notice to provide a license to Beoro Therapeutics for a cancer drug...

https://www.federalregister.gov/documents/2018/06/07/2018-12179/prospective-grant-of-an-exclusive-patent-license-the-development-of-an-anti-bcma-immunotoxin-for-the

There's not a lot of publicly available information about Beoro and wondering why the agency chose this company. What info exists to give taxpayers confidence that such a license would be awarded to a company with the expertise and capabilities to develop the technology?

It seems one of the Beoro folks - Gerhard Niederfellner - worked at Roche. Can you confirm this and provide some insight into how this company was chosen?

Thanks
ed silverman
STAT / Pharmalot
973-493-7851
www.statnews.com/pharmalot/

From: Myles, Renate (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7D317F5626934585B3692A1823C1B522-MYLESR]
Sent: 6/21/2018 8:22:36 PM
To: Lambertson, David (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3c95b34f709746a8a2553ce54e74ace2-lambertsond]; Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]; Hatch, Shannon (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=562f6d8791de4aa1837656c095c280a2-hatchsp]; NCI Press Officers [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=83b2a0d208d24786b9432a82ef45fed1-ncipressoff]
CC: Rodriguez, Richard (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8092cb5394e04733ac0d4d84d25f65e5-rodrigr]
Subject: RE: quick question from a journalist

Okay, great. Shannon and team, punting to you for handling. Response has already been written (see below).

From: Lambertson, David (NIH/NCI) [E]
Sent: Thursday, June 21, 2018 4:21 PM
To: Myles, Renate (NIH/OD) [E] <mylesr@mail.nih.gov>; Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>; Hatch, Shannon (NIH/NCI) [E] <hatchsp@mail.nih.gov>; NCI Press Officers <ncipressofficers@mail.nih.gov>
Cc: Rodriguez, Richard (NIH/NCI) [E] <richard.rodriguez@nih.gov>
Subject: RE: quick question from a journalist

I'm ok with the press office handling it. I'm technically out of the office through the weekend, so my attention to e-mail will be sporadic at best.

David A. Lambertson, Ph.D.
Senior Technology Transfer Manager
Technology Transfer Center
National Cancer Institute/NIH
david.lambertson@nih.gov
http://ttc.nci.nih.gov/

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From: Myles, Renate (NIH/OD) [E]
Sent: Thursday, June 21, 2018 4:20 PM
To: Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>; Hatch, Shannon (NIH/NCI) [E] <hatchsp@mail.nih.gov>; NCI Press Officers <ncipressofficers@mail.nih.gov>
Cc: Lambertson, David (NIH/NCI) [E] <david.lambertson@nih.gov>; Rodriguez, Richard (NIH/NCI) [E] <richard.rodriguez@nih.gov>
Subject: RE: quick question from a journalist

Hi Dave:

I'm looping in Shannon Hatch and the NCI press team. If you agree that this response is appropriate for Ed's questions, Shannon and team can clear it and once cleared, you can provide it to Ed. Or, if you prefer, the NCI press office can be the go between. Your choice.

The proposed exclusive license from the NCI for the technology described in the Federal Register notice has a limited field of use. This proposed exclusive license does not prevent the technology from being licensed for the development of other cancer therapies. There are multiple other ways this technology could be used that are not subject to this proposed license. This is the only license application we received for this use of the technology. The agency has thoroughly reviewed the business plan and qualifications of the company, which have been deemed to have met the statutory criteria for an exclusive license. Federal regulations require that a "Notice of a prospective license, identifying the invention and the prospective licensee, has been published in the Federal Register, providing opportunity for filing written objections within at least a 15-day period;" 37 USC sec 404.7(a)(1)(i) The agency does not begin the negotiation of an exclusive license, including financial terms, until it has considered all comments and any competing licenses that are submitted during the notice period. After considering any such responses, a final decision will be made. We cannot provide information provided by the applicant because under 35 USC sec 209 "any such [business] plan shall be treated by the Federal agency as "privileged and confidential" and not subject to disclosure under section 552 of title 5 [the FOIA statute]."

Thanks,
Renate

From: Rohrbaugh, Mark (NIH/OD) [E]
Sent: Thursday, June 21, 2018 4:17 PM
To: Myles, Renate (NIH/OD) [E] <mylesr@mail.nih.gov>
Cc: Lambertson, David (NIH/NCI) [E] <david.lambertson@nih.gov>; Rodriguez, Richard (NIH/NCI) [E] <richard.rodriguez@nih.gov>
Subject: FW: quick question from a journalist

Looks good to me. Thanks for your help Dave.

From: Myles, Renate (NIH/OD) [E]
Sent: Thursday, June 21, 2018 4:10 PM
To: Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>
Subject: RE: quick question from a journalist

See suggested changes. If you're okay with this, perhaps you can loop me in with David and I'll loop the NCI press office in to handle the response to Ed.

From: Rohrbaugh, Mark (NIH/OD) [E]
Sent: Thursday, June 21, 2018 4:00 PM
To: Myles, Renate (NIH/OD) [E] <mylesr@mail.nih.gov>
Subject: RE: quick question from a journalist

b5

From: Myles, Renate (NIH/OD) [E]
Sent: Thursday, June 21, 2018 3:33 PM
To: Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>
Subject: RE: quick question from a journalist

b5

From: Rohrbaugh, Mark (NIH/OD) [E]
Sent: Thursday, June 21, 2018 3:32 PM
To: Myles, Renate (NIH/OD) [E] <mylesr@mail.nih.gov>
Subject: RE: quick question from a journalist

b5

From: Myles, Renate (NIH/OD) [E]
Sent: Thursday, June 21, 2018 3:25 PM
To: Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>
Subject: RE: quick question from a journalist

So, we should respond to Ed. b5

b5

From: Rohrbaugh, Mark (NIH/OD) [E]
Sent: Thursday, June 21, 2018 3:08 PM
To: Myles, Renate (NIH/OD) [E] <mylesr@mail.nih.gov>
Subject: FW: quick question from a journalist

b5

From: Lambertson, David (NIH/NCI) [E]
Sent: Thursday, June 21, 2018 3:05 PM
To: Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>
Cc: Rodriguez, Richard (NIH/NCI) [E] <richard.rodriguez@nih.gov>
Subject: FW: quick question from a journalist

Hi Mark,

I also received this question from a non-KEI entity. b5

Thanks,

David A. Lambertson, Ph.D.
Senior Technology Transfer Manager
Technology Transfer Center
National Cancer Institute/NIH
david.lambertson@nih.gov
http://ttc.nci.nih.gov/

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From: Silverman, Ed [mailto:ed.silverman@statnews.com]
Sent: Thursday, June 21, 2018 11:25 AM
To: Lambertson, David (NIH/NCI) [E] <david.lambertson@nih.gov>
Subject: quick question from a journalist

Hi Dave,

My name is Ed Silverman and I run the Pharmalot blog at The Boston Globe's STAT health news site, where I track the pharmaceutical industry.

A quick question about the NIH notice to provide a license to Beoro Therapeutics for a cancer drug...

https://www.federalregister.gov/documents/2018/06/07/2018-12179/prospective-grant-of-an-exclusive-patent-license-the-development-of-an-anti-bcma-immunotoxin-for-the

There's not a lot of publicly available information about Beoro and wondering why the agency chose this company. What info exists to give taxpayers confidence that such a license would be awarded to a company with the expertise and capabilities to develop the technology?

It seems one of the Beoro folks - Gerhard Niederfellner - worked at Roche. Can you confirm this and provide some insight into how this company was chosen?

Thanks
ed silverman
STAT / Pharmalot
973-493-7851
www.statnews.com/pharmalot/

From: Lambertson, David (NIH/NCI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=3C95B34F709746A8A2553CE54E74ACE2-LAMBERTSOND]
Sent: 6/21/2018 8:20:10 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]; Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]
CC: Rodriguez, Richard (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8092cb5394e04733ac0d4d84d25f65e5-rodrigr]
Subject: RE: quick question from a journalist

I'm ok with it. I'll keep my eye on my e-mail every so often even though I am technically out, in case something comes up that needs immediate attention.

David A. Lambertson, Ph.D.
Senior Technology Transfer Manager
Technology Transfer Center
National Cancer Institute/NIH
david.lambertson@nih.gov
http://ttc.nci.nih.gov/

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From: Rohrbaugh, Mark (NIH/OD) [E]
Sent: Thursday, June 21, 2018 4:17 PM
To: Myles, Renate (NIH/OD) [E] <mylesr@mail.nih.gov>
Cc: Lambertson, David (NIH/NCI) [E] <david.lambertson@nih.gov>; Rodriguez, Richard (NIH/NCI) [E] <richard.rodriguez@nih.gov>
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From: Myles, Renate (NIH/OD) [E]
Sent: Thursday, June 21, 2018 4:10 PM
To: Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>
Subject: RE: quick question from a journalist

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From: Rohrbaugh, Mark (NIH/OD) [E]
Sent: Thursday, June 21, 2018 4:00 PM

To: Myles, Renate (NIH/OD) [E] <mylesr@mail.nih.gov>
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Subject: RE: quick question from a journalist

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From: Rohrbaugh, Mark (NIH/OD) [E]
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To: Myles, Renate (NIH/OD) [E] <mylesr@mail.nih.gov>
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Sent: Thursday, June 21, 2018 3:05 PM
To: Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>
Cc: Rodriguez, Richard (NIH/NCI) [E] <richard.rodriguez@nih.gov>
Subject: FW: quick question from a journalist

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David A. Lambertson, Ph.D.
Senior Technology Transfer Manager
Technology Transfer Center
National Cancer Institute/NIH
david.lambertson@nih.gov
http://ttc.nci.nih.gov/

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Sent: Thursday, June 21, 2018 11:25 AM
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https://www.federalregister.gov/documents/2018/06/07/2018-12179/prospective-grant-of-an-exclusive-patent-license-the-development-of-an-anti-bcma-immunotoxin-for-the

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It seems one of the Beoro folks - Gerhard Niederfellner - worked at Roche. Can you confirm this and provide some insight into how this company was chosen?

Thanks
ed silverman
STAT / Pharmalot
973-493-7851
www.statnews.com/pharmalot/

From: Berkley, Dale (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/CN=OD/CN=BERKLEYD]
Sent: 4/20/2016 4:55:03 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=OD/cn=ROHRBAUM]
Subject: RE: Response to KEI re BNCT 19April 2016.docx

Mark:

Thanks for this.

b5

Best, Dale

Dale D. Berkley, Ph.D., J.D.
Office of the General Counsel, PHD, NIH Branch
Bldg. 31, Rm. 47
Bethesda, MD 20892
301-496-6043
301-402-2528(Fax)

This message is intended for the exclusive use of the recipient(s) named above. It may contain information that is PROTECTED or PRIVILEGED, and it should not be disseminated, distributed, or copied to persons not authorized to receive such information.

From: Rohrbaugh, Mark (NIH/OD) [E]
Sent: Tuesday, April 19, 2016 4:13 PM
To: Berkley, Dale (NIH/OD) [E] <BerkleyD@OD.NIH.GOV>
Subject: FW: Response to KEI re BNCT 19April 2016.docx

Dale:

Here is a specific objection to an exclusive license with questions about the licensing conditions and proposed response with my edits. b5 b5

Please let me know your thoughts on this,
Mark

From: Shmilovich, Michael (NIH/NHLBI) [E]
Sent: Tuesday, April 19, 2016 2:24 PM
To: Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>
Subject: RE: Response to KEI re BNCT 19April 2016.docx

From: Rohrbaugh, Mark (NIH/OD) [E]
Sent: Tuesday, April 19, 2016 12:03 PM
To: Shmilovich, Michael (NIH/NHLBI) [E]
Subject: RE: Response to KEI re BNCT 19April 2016.docx

Can you send me his objection please? I don't think we need to address all the questions, which makes it easier.

From: Shmilovich, Michael (NIH/NHLBI) [E]
Sent: Tuesday, April 19, 2016 10:54 AM
To: Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>
Subject: Response to KEI re BNCT 19April 2016.docx

My 2c

From: Rohrbaugh, Mark (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/CN=OD/CN=ROHRBAUM]
Sent: 12/20/2016 12:13:55 PM
To: Leff, Michelle (NIH/NIDA/IRP) [E] [/O=NIH/OU=NIHEXCHANGE/cn=NIDAIntra/cn=MLeff]
Subject: Re: NYT: Harnessing the U.S. Taxpayer to Fight Cancer and Make Profits
Attachments: image008.jpg; image002.jpg; image009.jpg; image010.jpg; image005.jpg; image011.jpg; image007.jpg

Thx. Better than some other media, and they included important points we made but still do not present equally the opposing view that march in is not an authority to control prices.

Sent from my iPhone

On Dec 20, 2016, at 7:10 AM, Leff, Michelle (NIH/NIDA/IRP) [E] <MLeff@intra.nida.nih.gov> wrote:

> Just finished reading the article with my morning coffee. Congratulations on the interview. Were you pleased with the coverage?
>
> M
>
> Michelle Kim Leff, MD, MBA
> CAPT, USPHS
> NIDA Technology Development Coordinator
> Chief of Staff
> Office of the Scientific Director (OSD)
> IRP/NIDA/NIH/DHHS
>
> BRC, Suite 200, Room 04A515
> 251 Bayview Blvd.
> Baltimore MD 21224
>
> Email: Michelle.Leff@nih.gov
> Phone: 443.740.2463 (OSD)
> Direct Line: b6
> Cell: b6
>
> **From:** Rohrbaugh, Mark (NIH/OD) [E]
> **Sent:** Tuesday, December 20, 2016 7:06 AM
> **To:** NIH TDC Long <niaaatdcl-l@mail.nih.gov>; OD-OTT <OD-OTT@OD.NIH.GOV>
> **Subject:** Fwd: NYT: Harnessing the U.S. Taxpayer to Fight Cancer and Make Profits
>
> Sent from my iPhone
>
> Begin forwarded message:
>
> > **From:** "Myles, Renate (NIH/OD) [E]" <mylesr@od.nih.gov>
> > **Date:** December 19, 2016 at 9:33:05 PM EST
> > **To:** "Collins, Francis (NIH/OD) [E]" <collinsf@od.nih.gov>, NIH Director's Executive Committee <OD-SmallStaff@mail.nih.gov>
> > **Cc:** "Jackson, Calvin (NIH/OD) [E]" <JACKSONC@od31tm1.od.nih.gov>, OCPLPressTeam <OCPLPressTeam@od.nih.gov>, "Rohrbaugh, Mark (NIH/OD) [E]" <RohrBauM@OD.NIH.GOV>, "Kassilke, Deborah (NIH/OD) [E]" <deborah.kassilke@nih.gov>
> > **Subject: NYT: Harnessing the U.S. Taxpayer to Fight Cancer and Make Profits**

New York Times

Health

Harnessing the U.S. Taxpayer to Fight Cancer and Make Profits

By MATT RICHTEL and ANDREW POLLACK DEC. 19, 2016

Dr. Steven Rosenberg, left, who has led the surgery branch at the National Cancer Institute for 42 years, and Dr. Arie Belldegrun, the founder of Kite Pharma. Credit Jesse Dittmar (left) and Emily Berl (right) for The New York Times

Enthusiasm for cancer immunotherapy is soaring, and so is Arie Belldegrun's fortune.

Dr. Belldegrun, a physician, co-founded Kite Pharma, a company that could be the first to market next year with a highly anticipated new immunotherapy treatment. But even without a product, Dr. Belldegrun has struck gold.

His stock in Kite is worth about $170 million. Investors have profited along with him, as the company's share price has soared to about $50 from an initial price of $17 in 2014.

The results reflect widespread excitement over immunotherapy, which harnesses the body's immune system to attack cancer and has rescued some patients from near-certain death. But they also speak volumes about the value of Kite's main scientific partner: the United States government.

Kite's treatment, a form of immunotherapy called CAR-T, was initially developed by a team of researchers at the National Cancer Institute, led by a longtime friend and mentor of Dr. Belldegrun. Now Kite pays several million a year to the government to support continuing research dedicated to the company's efforts.

The relationship puts American taxpayers squarely in the middle of one of the hottest new drug markets. It also raises a question: Are taxpayers getting a good deal?

Defenders say that the partnership will likely bring a lifesaving treatment to patients, something the government cannot really do by itself, and that that is what matters most.

Critics say that taxpayers will end up paying twice for the same drug — once to support its development and a second time to buy it — while the company reaps the financial benefit.

"If this was not a government-funded cancer treatment — if it was for a new solar technology, for example — it would be scandalous to think that some private investors are reaping massive profits off a taxpayer-funded invention," said James Love, director of Knowledge Ecology International, an advocacy group concerned with access to medicines.

Photo

Dr. Rosenberg and Dr. Belldegrun in the mid-1980s. Dr. Belldegrun became a research fellow for Dr. Rosenberg at the cancer institute in 1985. Credit Kite Pharma

The debate goes squarely to one of the nation's most vexing challenges: rising health care and drug prices. Kite is one of a growing number of drug and biotech companies relying on federal laboratories. Analysts expect the company to charge at least $200,000 for the new treatment, which is intended as a one-time therapy for patients.

While the law allows the government to demand drug-price concessions from its private-sector partners, the government has declined to do so with Kite and generally disdains the practice.

Insisting on lower prices, federal researchers say, would drive away innovative partners that speed the drug-development process and benefit patients. But with the government doing so much pivotal research, others say that the private sector cannot afford to walk away.

"The market is so reliant on the knowledge and know-how that comes out of the government and academic labs," said Dr. Aaron Kesselheim, director of the Program on Regulation, Therapeutics and Law at Brigham & Women's Hospital in Boston.

Price curbs, he said, "would not suddenly lead to a total abandonment of this pipeline. It couldn't possibly."

Drug makers would be especially unlikely to turn away from immunotherapy, where the promising science has set off a "gold rush mentality," according to Mark Edwards of Bioscience Advisors, a company which tracks pharmaceutical licensing deals.

The National Institutes of Health, the parent agency of the National Cancer Institute, currently has about 400 cooperative research agreements with companies, and licenses hundreds of patented inventions for private-sector development.

Kite executives and national health officials characterize their partnership as a model arrangement in a system established by Congress three decades ago. The system has given birth to the cancer drug Taxol, the AIDS drug Prezista, two cervical cancer vaccines and a widely used test for H.I.V. infection, among other innovations.

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Photo

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Dr. Rosenberg in his lab at the cancer institute in Bethesda, Md. Partnerships between government labs and drug companies are "absolutely essential or many discoveries will not see the light of day," he said. Credit Jesse Dittmar for The New York Times

Kite's first drug, called KTE-C19, could help thousands of patients each year in the United States with certain blood cancers. If it succeeds, it could generate sales of $1 billion to $2 billion annually, according to Wall Street analysts, making it among the most lucrative drugs to come from government research.

But the government's share of any Kite success would be modest, much lower than some academic research groups have wrangled in immunotherapy deals worth hundreds of millions of dollars. Federal officials counter that the reward to the taxpayer is not money but the drug itself.

"This is exactly the way things should work," said Dr. Steven Rosenberg, who has led the surgery branch at the National Cancer Institute for 42 years and led development of Kite's drug. Such partnerships, he said, are "absolutely essential or many discoveries will not see the light of day."

Moreover, government officials say, companies in such deals must take significant financial risks and expenditures on their own, without any guarantee that the drug will be approved.

Kite says it has spent more than $200 million on research and development, including running larger clinical trials than those conducted by the cancer institute, and recently spent about $30 million to build a factory that will be able to make treatments for up to 5,000 patients a year.

Setting the price of the drug, Dr. Rosenberg said, “is for the marketplace.”

A Public-Private Partnership

Like many business deals, this one began with a personal relationship — in this case between Dr. Rosenberg and Dr. Belldegrun.

After finishing medical school in his native Israel, performing surgery in helicopters for the Israeli armed forces, and completing residency at Brigham & Women’s Hospital, Dr. Belldegrun became a research fellow for Dr. Rosenberg at the N.C.I. It was 1985, and Dr. Belldegrun was put to work on a new project of Dr. Rosenberg’s — extracting tumor-fighting immune cells from cancer patients, multiplying them in the laboratory, and putting them back in.

“He was one of the more outstanding fellows to come through,” said Dr. Rosenberg, 76, who is widely considered a cancer research luminary.

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Photo

Dr. Belldegrun, center, at the Nasdaq stock exchange, where Kite Pharma is listed. The company was founded in 2009 and went public in 2014. Credit Nasdaq, 2016

When the fellowship ended in 1988, Dr. Belldegrun became a prominent surgeon at the University of California, Los Angeles, but the two men stayed in touch. Eventually, Dr. Belldegrun, 67, got the entrepreneurial bug. He co-founded a biotech company, Agensys, which was acquired by a bigger company for more than $500 million. He was also involved with Cougar Biotechnology, which developed the prostate cancer drug Zytiga and was acquired by Johnson & Johnson for $1 billion in May 2009. A month later, Dr. Belldegrun formed Kite with a group of colleagues and investors to pursue cancer immunotherapy.

That same month, a Florida marine contractor named Eric Karlson, whose non-Hodgkin's lymphoma was advancing despite four prior treatments, became the first patient treated by Dr. Rosenberg with what would eventually become KTE-C19. The treatment entailed removing some of Mr. Karlson's immune system T cells from his blood, genetically engineering them to recognize and fight his cancer, multiplying the T cells to huge numbers in the laboratory and transferring them back into his body. After two such treatments, Mr. Karlson remains alive and cancer-free eight years later.

Kite initially thought it would pursue an approach to immunotherapy known as cancer vaccines, but in 2010, Dr. Belldegrun visited Dr. Rosenberg and was shown the X-rays of Mr. Karlson and of a second patient.

Dr. Belldegrun was bowled over. "I had no doubt that this is going to be a drug and, more than that, it will become a platform for multiple products," he recalled. "We never looked back."

Over the next two years, the National Cancer Institute worked out a deal with Kite that was signed in 2012. It was the first of eight contracts between the government and the company that generally take two forms.

In one type of contract, Kite licenses patented inventions and agrees to pay the government royalties, roughly 5 percent of sales of any commercial product arising from a particular patent. However, there is no such license specifically for KTE-C19 because the underlying treatment was not patented by the N.C.I., so royalties will be minimal.

Officials say the agency did not apply for a patent because the treatment was similar to what others had been developing. Also, at the time the treatment was first created, in 2007, immunotherapy was considered to have dim commercial prospects.

"Back then, we didn't even think about commercial aspects," said Dr. James N. Kochenderfer, a scientist at the agency who designed the treatment when working in Dr. Rosenberg's group.

Under the second type of contract, known as a cooperative research and development agreement, Kite provides money to the N.C.I. to support research. Kite is now paying $3 million a year to Dr. Rosenberg's lab and has provided $7.5 million to it in total since 2012. Based on its regulatory filings, Kite is paying $7.8 million a year for research agreements and licenses in total, with at least $4 million of that going to the cancer institute and the rest to academic or corporate partners.

The taxpayer has invested, too. Dr. Rosenberg estimated that the government has spent roughly $10 million over the years on what has become KTE-C19. He said Kite's $3 million a year is about equal to the taxpayer funding in that area and has helped speed research.

These days, researchers from Kite and the cancer institute, typically including Dr. Rosenberg and Dr. Belldegrun, confer by conference call every other Thursday for 90 minutes. Kite employees have spent long periods at the N.C.I., learning how to manufacture the therapy and how to treat patients in advance with chemotherapy.

"We shouldn't underestimate the value and the importance of N.I.H., not only to Kite but to the whole field of engineered T-cell therapy," Dr. Belldegrun said. When Kite signed its first deal with the cancer agency, he said, it "tapped into six years of monumental work that they had done."

Some immunotherapy competitors marvel at the company's coup in tapping into the agency's expertise. "They got 20 years of research all together in one scoop," said Dr. Carlos Paya, chief executive of Immune Design, which is pursuing a different approach.

But government officials say few, if any, other companies were interested in the technology at the time Dr. Belldegrun came calling. Dr. Rosenberg said that before Kite, a few companies, including Johnson & Johnson, had looked at an earlier version of his technology but were wary because treatment involved processing each patient's cells.

Government-developed technology available to be licensed to companies is posted on the website of the National Institutes of Health. And when the agency intends to grant a license to a particular company, it publishes that in the Federal Register, inviting public comment and possible competing offers. Both steps were taken in the case of Kite, officials said.

Kite did not get everything the cancer institute has developed in the field. Some other companies, including Opus Bio and Bluebird Bio, got rights to some products, in part because the companies had special expertise that the agency's researchers desired. But Kite seems to have gotten the balance of them and N.C.I. technology accounts for the majority of its pipeline of possible products, though the company is diversifying.

Photo

A slide that Kite Pharma used in presentations to potential investors pointed out the company's relationship with Dr. Rosenberg.

Dr. Rosenberg professes no interest in the business side of the Kite relationship. He does not own stock in any company, even Kite, though he could get up to $150,000 a year in patent royalties if some of Kite's efforts pay off.

Dr. Belldegrun, in contrast to his mentor, has commercial flair. He is known for his sharp business suits, lives in the Bel-Air neighborhood of Los Angeles, and seems as comfortable on Wall Street or in high society as in the operating room.

Kite's relationship with the N.C.I. is an important part of its appeal to investors. In some presentations, Dr. Belldegrun has shown a photograph of himself with Dr. Rosenberg in their younger days. And he persuaded Dr. Rosenberg to speak at Kite's first big meeting for investors in June 2015, the only time he has ever spoken to Wall Street.

In emails obtained through a Freedom of Information Act request by Knowledge Ecology International, Dr. Belldegrun praised Dr. Rosenberg's talk and sent him copies of investment reports from the conference written by Wall Street analysts.

"Thank you for making the effort to come to NY," Dr. Belldegrun wrote. "I heard only raving reviews about your presence and presentation."

A ‘Reasonable’ Question

The reliance of private companies on government-funded research goes well beyond obvious cases like Kite. In many instances, companies work with universities or medical centers that, in turn, have been funded from the $32 billion annual budget of the National Institutes of Health.

Kite’s two main competitors, Novartis and Juno Therapeutics, for instance, derived similar immunotherapy treatments largely from academic institutions, developed at least in part with government funding. Novartis has a relationship with the University of Pennsylvania, and Juno with the Memorial Sloan Kettering Cancer Center, the Fred Hutchinson Cancer Research Center and Seattle Children’s Hospital.

“For the most important drugs you’ll see some public-sector involvement,” said Bhaven Sampat, an associate professor of health policy and management at Columbia University. He was one author of a study that found that 9 percent of all drugs approved between 1988 and 2005 were based directly on a patent held by the public sector. But 47.8 percent of the drugs relied at least indirectly on some federally funded research.

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Photo

Eric Karlson at his home on Marco Island, Fla., this month. Mr. Karlson’s non-Hodgkin’s lymphoma was successfully treated by Dr. Rosenberg with what would eventually become KTE-C19. Credit Scott McIntyre for The New York Times

The figures were higher for more medically important drugs: 17.4 percent had a direct public-sector patent, while 64.5 percent had at least an indirect public-sector influence.

These figures are up sharply from before the 1980s. Such partnerships and licensing deals were encouraged by the 1980 Bayh-Dole and Stevenson-Wydler Acts, and the 1986 Federal Technology Transfer Act. The laws are credited with jump-starting the biotechnology industry.

But from the beginning, some people questioned whether taxpayers were getting a bad deal.

Perhaps the best-known drug developed from a cooperative research and development agreement — the cancer drug Taxol — was the subject of several congressional hearings in the early 1990s that investigated whether the drug's maker, Bristol-Myers Squibb, charged too much and whether the government recouped enough of its investment. In the end, the pricing was left unchanged.

The N.I.H. argues that if it imposes pricing restrictions, it won't get partners. In fact, in 1995, it struck from its negotiating tactics a goal that prices be "reasonable."

"Companies will not take technologies from us if we say the government will decide in the future what the price will be," said Mark Rohrbaugh, who ran the technology transfer office at the institutes from 2001 to 2013 and is now an adviser to the agency. After the "reasonable price" clause was struck, he said, there was a threefold increase in partnership deals.

The N.I.H. can collect royalties from successful products to help offset the costs of the research, but so far these royalties have been small, amounting to an estimated $135 million in the last fiscal year from 870 licenses, with the bulk of the money coming from a small number of drugs.

"We're not preoccupied with financial value," Dr. Rohrbaugh said. "Our mission is treatment of people and improving public health."

In that regard, the government's bet on a small company like Kite, which might have seemed risky, appears to be paying off so far. Dr. Belldegrun has largely delivered on promises to raise money, assemble an experienced staff, build the factory, conduct clinical trials and begin to apply for regulatory approval. Once considered the underdog to Novartis and Juno, Kite might be the first reach the market.

Photo

Scans of Mr. Karlson’s body before and after his treatment. In the cross-sections on the left, the arrows point to signs of lymphoma in areas such as his armpits, chest, spleen and pelvis. Credit National Cancer Institute

Academic centers and companies often drive harder bargains in licensing technology. In some cases, academic centers own a stake in a company they license technology to, allowing them to reap a financial windfall if the company does well. Both the Hutchinson cancer center and Sloan Kettering have owned stock in Juno and are entitled to substantial payments — up to $350 million and $150 million — if Juno’s stock reaches certain levels.

The N.I.H. does not take equity positions in companies to avoid an appearance of a conflict of interest. So to critics of the government deals, drug prices are crucial to understanding taxpayer value. After all, they ask, is a drug truly widely available — which is what the government says is its measure of success — if it costs too much for some people?

Rachel Sachs, an associate law professor at Washington University in St. Louis and expert in innovation policy, said the government had every right to seek price concessions. She noted that the government, through Medicare and Medicaid, was effectively buying its inventions back from itself. “The public is paying for the research and to the extent that many people, if not most, will pay through public insurance, we’re paying again,” she said.

Hillary Clinton, in her campaign for president, promised to set new rules for federal support of research so that Americans "get the value they deserve" for the money taxpayers spend in supporting research. It is not clear how President-elect Donald J. Trump will approach these issues; he has said he favors reducing health care costs, but Republicans, who control Congress, too, have opposed government involvement in price setting.

One mechanism to control pricing already exists. It is called march-in rights, and it lets the N.I.H. take back control of a patent on an invention made with federal funding if the drug is not being made available to the public on reasonable terms. The tool has gone unused.

Earlier this year, Knowledge Ecology International and another advocacy group, the Union for Affordable Cancer Treatment, petitioned the agency to exercise march-in rights on Xtandi, a prostate cancer drug that was developed by federally funded researchers at U.C.L.A. It said the price in the United States of about $129,000 a year, two to four times that in other developed countries, meant the drug was not reasonably available. The effort was supported by other public interest groups and some Democratic members of Congress.

U.C.L.A. made more than $500 million by selling its royalty rights to the drug. But the N.I.H. declined to exercise its march-in rights on Xtandi, arguing that it was not qualified to judge whether a drug's price is reasonable and that a high price does not mean a drug is not being made available to the public.

"N.I.H. has made it clear that its job is not to decide prices of drugs, period," Dr. Rohrbaugh said

Kite says it has not decided what to charge for KTE-C19, but Dr. Belldegrun hinted that Kite's therapy might be relatively expensive because ideally it would be a single treatment that would cure the patient, not a drug that would have to be taken continuously. He added that Kite would take steps to make sure that everyone who needed the drug could get it.

Meantime, the relationship between Kite and the National Cancer Institute is expanding to develop treatments for other cancers, including one technique Dr. Rosenberg thinks could be used to attack solid tumors like colon, breast and lung cancer.

"The potential for broad applicability is huge," he said.

That could mean many lives saved and maybe more billion-dollar drugs for Kite and its investors, with the American taxpayer right in the middle of the deal.

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From: Rohrbaugh, Mark (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/CN=OD/CN=ROHRBAUM]
Sent: 3/25/2016 4:26:40 PM
To: Hammersla, Ann (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=Recipients/cn=hammerslaa]
Subject: Fwd: WF 345473 - Response Creation due 4/1
Attachments: email.pdf; ATT00001.htm; incoming.pdf; ATT00002.htm

I will draft something and send it to you. b5

Sent from my iPhone

Begin forwarded message:

> **From:** "Carr, Sarah (NIH/OD) [E]" <CarrS@OD.NIH.GOV>
> **Date:** March 25, 2016 at 12:22:53 PM EDT
> **To:** "Rohrbaugh, Mark (NIH/OD) [E]" <RohrBauM@OD.NIH.GOV>
> **Cc:** "Plude, Denise (NIH/OD) [E]" <pludede@mail.nih.gov>
> **Subject: FW: WF 345473 - Response Creation due 4/1**
>
> Mark,
>
> See instructions below.
>
> Sarah
>
> **From:** Plude, Denise (NIH/OD) [E]
> **Sent:** Friday, March 25, 2016 12:19 PM
> **To:** Carr, Sarah (NIH/OD) [E] <CarrS@OD.NIH.GOV>
> **Subject:** WF 345473 - Response Creation due 4/1
>
> **Work Folder Information**
> **Work Folder:** WF 345473
> **Process:** Response Creation
> **Program Analyst:** Twyman, Leslie (NIH/OD) [E]
> **Due Date:** April 01, 2016
> **WF Subject:** Supports the Union for Affordable Cancer Treatment and Knowledge Ecology International's request that the NIH use the government's march-in rights in patents on the prostate cancer drug enzalutamide (marketed at Xtandi).
> **IC:** od_osp
> **From:** Ramachandran, Reshma
> **To:** Collins, Francis
> **Remarks:** Assigned to OSP to work with OER and OTT to prepare a Dir Sig response by noon on 4/1/16. Info copies to OER, OTT, NCI and OGC (DIR, DEPD, and DDSOP already received an info copy). Thank you, Leslie Twyman for Lisa Marshall (workfolder 345473).